an asserted utility, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement. Similarly, Office personnel must accept an opinion from a qualified expert that is based upon relevant facts whose accuracy is not being questioned; it is improper to disregard the opinion solely because of a disagreement over the significance or meaning of the facts offered.

Once a *prima facie* showing of no specific and substantial credible utility has been properly established, the applicant bears the burden of rebutting it. The applicant can do this by amending the claims, by providing reasoning or arguments, or by providing evidence in the form of a declaration under 37 CFR 1.132 or a patent or a printed publication that rebuts the basis or logic of the *prima facie* showing. If the applicant responds to the *prima facie* rejection, the Office personnel should review the original disclosure, any evidence relied upon in establishing the *prima facie* showing, any claim amendments, and any new reasoning or evidence provided by the applicant in support of an asserted specific and substantial credible utility. It is essential for Office personnel to recognize, fully consider and respond to each substantive element of any response to a rejection based on lack of utility. Only where the totality of the record continues to show that the asserted utility is not specific, substantial, and credible should a rejection based on lack of utility be maintained.

If the applicant satisfactorily rebuts a *prima facie* rejection based on lack of utility under § 101, withdraw the § 101 rejection and the corresponding rejection imposed under § 112, first paragraph.

Dated: December 29, 2000.

Q. Todd Dickinson,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 01-322 Filed 1-4-01; 8:45 am]

BILLING CODE 3510-16-U

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No. 991027288-0264-02]

RIN 0651-AB10

Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: These Guidelines will be used by USPTO personnel in their review of patent applications for compliance with the "written description" requirement of 35 U.S.C. 112, ¶ 1. These Guidelines supersede the "Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 'Written Description' Requirement" that were published in the Federal Register at 64 FR 71427, Dec. 21, 1999, and in the Official Gazette at 1231 O.G. 123, Feb. 29, 2000. These Guidelines reflect the current understanding of the USPTO regarding the written description requirement of 35 U.S.C. 112, ¶ 1, and are applicable to all technologies.

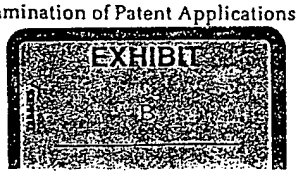
DATES: The Guidelines are effective as of January 5, 2001.

FOR FURTHER INFORMATION CONTACT: Stephen Walsh by telephone at (703) 305-9035, by facsimile at (703) 305-9373, by mail to his attention addressed to United States Patent and Trademark Office, Box 8, Washington, DC 20231, or by electronic mail at "stephen.walsh@uspto.gov"; or Linda Therkorn by telephone at (703) 305-8800, by facsimile at (703) 305-8825, by mail addressed to Box Comments, Commissioner for Patents, Washington, DC 20231, or by electronic mail at "linda.therkorn@uspto.gov."

SUPPLEMENTARY INFORMATION: As of the publication date of this notice, these Guidelines will be used by USPTO personnel in their review of patent applications for compliance with the "written description" requirement of 35 U.S.C. 112, ¶ 1. Because these Guidelines only govern internal practices, they are exempt from notice and comment rulemaking under 5 U.S.C. 553(b)(A).

Discussion of Public Comments

Comments were received from 48 individuals and 18 organizations in response to the request for comments on the "Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 'Written Description' Requirement" published in the Federal Register at 64 FR 71427, Dec. 21, 1999, and in the Official Gazette at 1231 O.G. 123, Feb. 29, 2000. The written comments have been carefully considered.



Overview of Comments

The majority of comments favored issuance of final written description guidelines with minor revisions. Comments pertaining to the written description guidelines are addressed in detail below. A few comments addressed particular concerns with respect to the associated examiner training materials that are available for public inspection at the USPTO web site (www.uspto.gov). Such comments will be taken under advisement in the revision of the training materials; consequently, these comments are not specifically addressed below as they do not impact the content of the Guidelines. Several comments raised issues pertaining to the patentability of ESTs, genes, or genomic inventions with respect to subject matter eligibility (35 U.S.C. 101), novelty (35 U.S.C. 102), or obviousness (35 U.S.C. 103). As these comments do not pertain to the written description requirement under 35 U.S.C. 112, they have not been addressed. However, the aforementioned comments are fully addressed in the "Discussion of Public Comments" in the "Utility Examination Guidelines" Final Notice, which will be published at or about the same time as the present Guidelines.

Responses to Specific Comments

(1) *Comment:* One comment stated that the Guidelines instruct the patent examiner to determine the correspondence between what applicant has described as the essential identifying characteristic features of the invention and what applicant has claimed, and that such analysis will lead to error. According to the comment, the examiner may decide what applicant should have claimed and reject the claim for failure to claim what the examiner considers to be the invention. Another comment suggested that the Guidelines should clarify what is meant by "essential features of the invention." Another comment suggested that what applicant has identified as the "essential distinguishing characteristics" of the invention should be understood in terms of *Fiers* v. *Revel*, 984 F.2d 1164, 1169, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993) ("Conception of a substance claimed *per se* without reference to a process requires conception of its structure, name,

formula, or definitive chemical or physical properties.").

Response: The suggestions have been adopted in part. The purpose of the written description analysis is to confirm that applicant had possession of what is claimed. The Guidelines have been modified to instruct the examiners to compare the scope of the invention claimed with the scope of what applicant has defined in the description of the invention. That is, the Guidelines instruct the examiner to look for consistency between a claim and what provides adequate factual support for the claim as judged by one of ordinary skill in the art from reading the corresponding written description.

(2) *Comment:* Two comments urge that *Regents of the University of California* v. *Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), is bad law and should not be followed by the USPTO because it conflicts with binding precedent, such as *Vas-Cath* v. *Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991). *Response:* The final Guidelines are based on the Office's current understanding of the law and are believed to be fully consistent with binding precedent of the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit. *Eli Lilly* is a precedential decision by the Court that has exclusive jurisdiction over appeals involving patent law. Accordingly, the USPTO must follow *Eli Lilly*. Furthermore, the USPTO does not view *Eli Lilly* as conflicting with *Vas-Cath*. *Vas-Cath* explains that the purpose of the written description requirement is to ensure that the applicant has conveyed to those of skill in the art that he or she was in possession of the claimed invention at the time of filing. *Vas-Cath*, 935 F.2d at 1563–64, 19 USPQ2d at 1117. *Eli Lilly* explains that a chemical compound's name does not necessarily convey a written description of the named chemical compound, particularly when a genus of compounds is claimed. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1405. The name, if it does no more than distinguish the claimed genus from all others by function, does not satisfy the written description requirement because "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus." *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. Thus, *Eli Lilly* identified a set of circumstances in which the words of the claim did not, without more, adequately convey to others that applicants had possession of what they claimed.

(3) *Comment:* Several comments urged that the Guidelines do not recognize the inconsistency between the original claim doctrine and the written description requirement as set out in *Fiers* and *Eli Lilly*. On the other hand, another comment asserts that there is no strong presumption that an originally filed claim constitutes an adequate written description of the claimed subject matter. Several comments indicate that *in haec verba* support should be sufficient to comply with the written description requirement. Two comments urge that the concept of constructive reduction to practice upon filing of an application has been ignored. *Response:* As noted above, the USPTO does not find *Fiers* and *Eli Lilly* to be in conflict with binding precedent. An original claim may provide written description for itself, but it still must be an *adequate* written description which establishes that the inventor was in possession of the invention. The "original claim doctrine" is founded on cases which stand for the proposition that originally filed claims are part of the written description of an application as filed, and thus subject matter which is present only in originally filed claims need not find independent support in the specification. *See, e.g., In re Koller*, 613 F.2d 819, 824, 204 USPQ 702, 706 (CCPA 1980) (later added claims of similar scope and wording were adequately described by original claims); *In re Gardner*, 480 F.2d 879, 880, 178 USPQ 149, 149 (CCPA 1973) ("Under these circumstances, we consider the original claim in itself adequate 'written description' of the claimed invention. It was equally a 'written description' * * * whether located among the original claims or in the descriptive part of the specification."). However, as noted in the preceding comment, *Eli Lilly* identified a set of circumstances in which the words of the claim did not, without more, adequately convey to others that applicants had possession of what they claimed. When the name of a novel chemical compound does not convey sufficient structural information about the compound to identify the compound, merely reciting the name is not enough to show that the inventor had possession of the compound at the time the name was written. The Guidelines indicate that there is a "strong presumption" that an adequate written description of the claimed invention is present when the application is filed, consistent with *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims."). In most cases, the statement that "an originally filed claim is its own written description," is borne out because the claim language conveys to others of skill in the art that the applicant was "in possession" of what is claimed. The Guidelines emphasize that the burden of proof is on the examiner to establish that a description as filed is not adequate and require the examiner to introduce sufficient evidence or technical reasoning to shift the burden of going forward with contrary evidence to the applicant.

(4) *Comment:* One comment stated that the Guidelines change the substance of the written description requirement to require some level of enablement. The comment stated that the *Eli Lilly* case should not be followed because its change in the quality of the description required is in conflict with precedent. Another comment suggested that to comply with the written description requirement, the description must both (i) demonstrate possession of the claimed invention by the applicant; and (ii) put the public in possession of the claimed invention. *Response:* As noted in the comment above, the USPTO is bound by the Federal Circuit's decision in *Eli Lilly*. The Guidelines have been revised to clarify that an applicant must provide a description of the claimed invention which shows that applicant was in possession of the claimed invention. The suggestion to emphasize that the written description requirement must put the public in possession of the invention has not been adopted because it removes much of the distinction between the written description requirement and the enablement requirement. Although the two concepts are entwined, they are distinct and each is evaluated under separate legal criteria. The written description requirement, a question of fact, ensures that the inventor conveys to others that he or she had possession of the claimed invention; whereas, the enablement requirement, a question of law, ensures that the inventor conveys to others how to make and use the claimed invention.

(5) *Comment:* One comment suggested that the Guidelines should provide examples of situations in which the written description requirement was met but the enablement requirement was not, and vice versa. Another comment stated that examiners often use enablement language in making

written description rejections.

Response: The enablement and written description requirements are not coextensive and, therefore, situations will arise in which one requirement is met but the other is not. Federal Circuit case law demonstrates many circumstances where enablement or written description issues, but not both, were before the Court. These Guidelines are intended to clarify for the examining corps the criteria needed to satisfy the written description requirement. For examples applying these Guidelines to hypothetical fact situations, see the "Synopsis of Application of Written Description Guidelines" (examiner training materials available on-line at *http://www.uspto.gov/web/menu/written.pdf*). These examples, as well as the examination form paragraphs and instructions on their proper use, provide the appropriate language examiners should use in making written description rejections.

(6) *Comment:* One comment disagreed with the statement in an endnote that "the fact that a great deal more than just a process is necessary to render a product invention obvious means that a great deal more than just a process is necessary to provide written description for a product invention." The comment indicated that the statement is overly broad and inconsistent with the "strong presumption that an adequate written description of the claimed invention is present when the application is filed." As an extreme case, for example, for product-by-process claims, nothing else would be needed to provide the written description of the product. *Response:* The endnote has been clarified and is now more narrowly drawn. However, there is no *per se* rule that disclosure of a process is sufficient to adequately describe the products produced by the process. In fact, *Fiers* v. *Revel* and *Eli Lilly* involved special circumstances where the disclosure of a process of making and the function of the product alone did not provide an adequate written description for product claims. Even when a product is claimed in a product-by-process format, the adequacy of the written description of the process to support product claims must be evaluated on a case-by-case basis.

(7) *Comment:* Several comments urge that actual reduction to practice, as a method of satisfying the written description requirement by demonstrating possession, has been over-emphasized. *Response:* The Guidelines have been clarified to state that describing an actual reduction to practice is one of a number of ways to show possession of the invention. Description of an actual reduction to practice offers an important "safe haven" that applies to all applications and is just one of several ways by which an applicant may demonstrate possession of the claimed invention. Actual reduction to practice may be crucial in the relatively rare instances where the level of knowledge and level of skill are such that those of skill in the art cannot describe a composition structurally, or specify a process of making a composition by naming components and combining steps, in such a way as to distinguish the composition with particularity from all others. Thus, the emphasis on actual reduction to practice is appropriate in those cases where the inventor cannot provide an adequate description of what the composition is, and a definition by function is insufficient to define a composition "because it is only an indication of what the [composition] does, rather than what it is." *Eli Lilly*, 119 F.3d at 1568, 43 USPQ at 1406. *See also Amgen Inc.* v. *Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991).

(8) *Comment:* One comment asserts that the citation to *Pfaff* v. *Wells Electronics, Inc.*, 525 U.S. 55, 48 USPQ2d 1641 (1998) is inappropriate and should be deleted because *Pfaff* is concerned with § 102(b) on-sale bar, not written description. Another comment suggested that the Guidelines should provide an explanation of how the "ready for patenting" concept of *Pfaff* should be used in determining compliance with the written description requirement. *Response:* The Guidelines state the general principle that actual reduction to practice is not required to show possession of, or to adequately describe, a claimed invention (although, as noted in the previous comment, an actual reduction to practice is crucial in relatively rare instances). An alternative is to show that the invention described was "ready for patenting" as set out in *Pfaff*. For example, a *description* of activities that demonstrates the invention was "ready for patenting" satisfies the written description requirement. As *Wertheim* indicates, "how the specification accomplishes this is not material." 541 F.2d at 262, 191 USPQ at 96.

(9) *Comment:* One comment stated that the written description of a claimed DNA should be required to include the complete sequence of the DNA and claims should be limited to the DNA sequence disclosed. *Response:* Describing the complete chemical structure, *i.e.*, the DNA sequence, of a claimed DNA is one method of satisfying the written description requirement, but it is not the only method. *See Eli Lilly*, 119 F.3d at 1566, 43 USPQ2d at 1404 ("An adequate written description of a DNA * * * requires a precise definition, *such as* by structure, formula, chemical name, or physical properties." (emphasis added, internal quote omitted)). Therefore, there is no basis for a *per se* rule requiring disclosure of complete DNA sequences or limiting DNA claims to only the sequence disclosed.

(10) *Comment:* One comment stated that it is difficult to envision how one could provide a description of sufficient identifying characteristics of the invention without physical possession of a species of the invention, and thus this manner of showing possession should be considered as a way to show actual reduction to practice. *Response:* This suggestion has not been adopted. The three ways of demonstrating possession as set forth in the Guidelines are merely exemplary and are not mutually exclusive. While there are some cases where a description of sufficient relevant identifying characteristics will evidence an actual reduction to practice, there are other cases where it will not. *See, e.g., Ralston Purina Co.* v. *Far-Mar-Co, Inc.*, 772 F.2d 1570, 1576, 227 USPQ 177, 180 (Fed. Cir. 1985) (disclosure taken with the knowledge of those skilled in the art may be sufficient support for claims).

(11) *Comment:* One comment stated that the Guidelines should be revised to indicate that the test of disclosure of sufficiently detailed drawings should be expanded to include structural claiming of chemical entities. *Response:* The suggestion has been adopted.

(12) *Comment:* One comment stated that the Guidelines should reflect that an inventor is in possession of the invention when the inventor demonstrably has at least a complete conception thereof, and that factors and attributes which provide proof of written description should include evidence typically provided to prove a complete conception. *Response:* The suggestion has not been adopted because the conception analysis typically involves documentary evidence in addition to the description of the invention in the application as filed. However, it is acknowledged that if evidence typically provided to prove a complete conception is present in the specification as filed, it would be sufficient to show possession. The Federal Circuit has stated "[t]he conception analysis necessarily turns on the inventor's ability to describe his invention with particularity. Until he can do so, he cannot prove possession

of the complete mental picture of the invention." *Burroughs Wellcome Co.* v. *Barr Labs., Inc.*, 40 F.3d 1223, 1228, 32 USPQ2d 1915, 1919 (Fed. Cir. 1994). As further noted by the Federal Circuit, in order to prove conception, "a party must show possession of every feature recited in the count, and that every limitation of the count must have been known to the inventor at the time of the alleged conception." *Coleman* v. *Dines*, 754 F.2d 353, 359, 224 USPQ 857, 862 (Fed. Cir. 1985).

(13) *Comment:* One comment indicated that a "possession" test does not appear in Title 35 of the U.S. Code and is not clearly stated by the Federal Circuit. Therefore, it is recommended that patent examiners be directed to use existing judicial precedent to make rejections of claims unsupported by a statutory written description requirement. *Response:* While the Federal Circuit has not specifically laid out a "possession" test, the Court has clearly indicated that possession is a cornerstone of the written description inquiry. *See, e.g., Vas-Cath, Inc.* v. *Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991); *see also Purdue Pharma L.P.* v. *Faulding Inc.*, 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000) ("[o]ne skilled in the art, reading the disclosure, must immediately discern the limitation at issue in the claims") (internal quote omitted). The possession test as set forth in the Guidelines is extrapolated from case law in a wide variety of technologies and is not intended to be limiting. Any rejections made by examiners will be made under 35 U.S.C. 112, ¶1, with supporting rationale. Final rejections are appealable if applicant disagrees and follows the required procedures to appeal.

(14) *Comment:* Two comments indicated that if the amino acid sequence for a polypeptide whose utility has been identified is described, then the question of possession of a class of nucleotides encoding that polypeptide can be addressed as a relatively routine matter using the understanding of the genetic code, and that the endnote addressing this issue should be revised. *Response:* The suggestion of these comments has been incorporated in the Guidelines and will be reflected in the training materials. However, based upon *In re Bell*, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994), this does not mean that applicant was in possession of any particular species of the broad genus.

(15) *Comment:* One comment disagreed with an endnote which stated that a laundry list disclosure of moieties does not constitute a written description of every species in a genus. Specifically, the comment indicates that if the existence of a functional genus is adequately described in the specification, a laundry list of the species within that genus must satisfy the written description requirement. *Response:* The suggestion to revise the endnote will not be adopted. A lack of adequate written description problem arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosure. This was aptly demonstrated in *In re Bell* and *In re Baird* where possession of a large genus did not put a person of ordinary skill in the art in possession of any particular species. *See also Purdue Pharma*, 230 F.3d at 1328, 56 USPQ2d at 1487 (because the original specification did not disclose the later claimed concentration ratio was a part of the invention, the inventors cannot argue that they are merely narrowing a broad invention).

(16) *Comment:* One comment suggested that in the majority of cases, a single species will support a generic claim, and that the Guidelines should emphasize this point. *Response:* The suggestion has been adopted to a limited degree. The Guidelines now indicate that a single species may, in some instances, provide an adequate written description of a generic claim when the description of the species would evidence to one of ordinary skill in the art that the invention includes the genus. Note, however, *Tronzo* v. *Biomet, Inc.*, 156 F.3d 1154, 47 USPQ2d 1829 (Fed. Cir. 1998), where the species in the parent application was held not to provide written description support for the genus in the child application.

(17) *Comment:* One comment asserted that the Guidelines should focus on the compliance of the claims, not the specification, with the written description requirement. *Response:* This suggestion will not be adopted. "The specification shall contain a written description of the invention." 35 U.S.C. 112. The claims are part of the specification. *Id.*, ¶ 2. If an adequate description is provided, it will suffice "whether located among the original claims or in the descriptive part of the specification." *In re Gardner*, 480 F.2d 879, 880, 178 USPQ 149 (CCPA 1973). The entire disclosure, including the specification, drawings, and claims, must be considered.

(18) *Comment:* One comment asserted that the Guidelines confuse "new matter," 35 U.S.C. 132, with the written description requirement, and that the same standard for written description should be applied to both original claims and new or amended claims. *Response:* The Guidelines indicate that for both original and amended claims, the inquiry is whether one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention at the time the application was filed.

(19) *Comment:* One comment suggested that the second paragraph of the section pertaining to determining what the claim as a whole covers should be deleted because it relates more to compliance with § 112, second paragraph, than with the written description requirement. *Response:* This suggestion will not be adopted. The claims must be construed and all issues as to the scope and meaning of the claim must be explored during the inquiry into whether the written description requirement has been met. The concept of treating the claim as a whole is applicable to all criteria for patentability.

(20) *Comment:* One comment suggested a different order for the general analysis for determining compliance with the written description requirement, starting with reading the claim, then the specification, and then determining whether the disclosure demonstrates possession by the applicant. *Response:* This suggestion will not be adopted. The claims must be construed as broadly as reasonable in light of the specification and the knowledge in the art. *See In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). Then the disclosure must be evaluated to determine whether it adequately describes the claimed invention, i.e., whether it conveys to a person having ordinary skill in the art that the applicant had possession of what he or she now claims.

(21) *Comment:* Several comments suggested that the Guidelines are unclear with regard to how the examiner should treat the transitional phrase "consisting essentially of." The comments also suggested that the endnote that explains "consisting essentially of" does not make clear how the use of this intermediate transitional language affects the scope of the claim. Several comments stated that the USPTO does not have legal authority to treat claims reciting this language as open (equivalent to "comprising"). Another comment suggested that the phrase "clear indication in the specification" be replaced with "explicit or implicit indication." *Response:* The transitional phrase "consisting essentially of" "excludes

ingredients that would 'materially affect the basic and novel characteristics' of the claimed composition." *Atlas Powder Co.* v. *E.I. DuPont de Nemours & Co.*, 750 F.2d 1569, 1574, 224 USPQ 409, 412 (Fed. Cir. 1984). The basic and novel characteristics of the claimed invention are limited by the balance of the claim. *In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 896 (CCPA 1963). However, during prosecution claims must be read broadly, consistent with the specification. *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). Thus, *for purposes of searching for and applying prior art in a rejection under 35 U.S.C. 102 or 103*, if the specification or the claims do not define the "basic and novel" properties of the claimed subject matter (or if such properties are in dispute), the broadest reasonable interpretation consistent with the specification is that the basic and novel characteristics are merely the presence of the recited limitations. *See, e.g., Janakirama-Rao*, 317 F.2d at 954, 137 USPQ at 895–96. This does not indicate that the intermediate transitional language is never given weight. Applicants may amend the claims to avoid the rejections or seek to establish that the specification provides definitions of terms in the claims that define the basic and novel characteristics of the claimed invention which distinguish the claimed invention from the prior art. When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of 'consisting essentially of,' applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). The language used in the Guidelines is consistent with *PPG Industries Inc.* v. *Guardian Industries Corp.*, 156 F.3d 1351, 1355, 48 USPQ2d 1351, 1355 (Fed. Cir. 1998) ("PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics.").

(22) *Comment:* One comment stated that the written description should "disclose the invention," including why the invention works and how it was developed. *Response:* This suggestion has not been adopted. An inventor does not need to know how or why the invention works in order to obtain a patent. *Newman* v. *Quigg*, 877 F.2d 1575, 1581, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989). To satisfy the enablement requirement of 35 U.S.C. 112, ¶1, an application must disclose the claimed invention in sufficient detail to enable a person of ordinary skill in the art to make and use the claimed invention. To satisfy the written description requirement of 35 U.S.C. 112, ¶ 1, the description must show that the applicant was in possession of the claimed invention at the time of filing. There is no statutory basis to require disclosure of why an invention works or how it was developed. "Patentability shall not be negatived by the manner in which the invention was made." 35 U.S.C. 103(a).

(23) *Comment:* One comment recommended that the phrases "emerging and unpredictable technologies" and "unpredictable art" be replaced with the phrase—inventions characterized by factors which are not reasonably predictable in terms of the ordinary skill in the art—. *Response:* The suggestion is adopted in part and the recommended phrase has been added as an alternative.

(24) *Comment:* One comment recommended that the phrase "conventional in the art" be replaced with—part of the knowledge of one of ordinary skill in the art—. *Response:* The suggestion is adopted in part and the recommended phrase has been added as an alternative. The standard of "conventional in the art" is supported by case law holding that a patent specification "need not teach, and preferably omits, what is well known in the art." *See Spectra-Physics, Inc.* v. *Coherent, Inc.*, 827 F.2d 1524, 1534, 3 USPQ2d 1737, 1743 (Fed. Cir. 1987); *Hybritech Inc.* v. *Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986). *See also Atmel Corp.* v. *Information Storage Devices, Inc.*, 198 F.3d 1374, 1382, 53 USPQ2d 1225, 1231 (Fed. Cir. 1999).

(25) *Comment:* One comment recommended that the Guidelines be amended to state that the appropriate skill level for determining possession of the claimed invention is that of a person of *ordinary* skill in the art. *Response:* The comment has not been adopted. The statutory language itself indicates that compliance with the requirements of 35 U.S.C. 112, ¶1, is judged from the standard of "any person skilled in the art." It is noted, however, that the phrases "one of skill in the art" and "one of ordinary skill in the art" appear to be synonymous. *See, e.g., Union Oil Co.* v. *Atlantic Richfield Co.*, 208 F.3d 989, 997, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000) ("The written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow *persons of ordinary skill in the art* to recognize that [he or she] invented what is claimed.' Thus, § 112, ¶ 1, ensures that, as of the filing date, the inventor conveyed with reasonable clarity to *those of skill in the art* that he was in possession of the subject matter of the claims." (citations omitted, emphasis added)).

(26) *Comment:* One comment stated that an endnote misstates the relevant law in stating that, to show inherent written descriptive support for a claim limitation, the inherent disclosure must be such as would be recognized by a person of ordinary skill in the art. The comment recommended that the endnote be amended to delete the reference to recognition by persons of ordinary skill and to cite *Pingree* v. *Hull*, 518 F.2d 624, 186 USPQ 248 (CCPA 1975), rather than *In re Robertson*, 169 F.3d 743, 49 USPQ2d 1949 (Fed. Cir. 1999). *Response:* The comment has not been adopted. Federal Circuit precedent makes clear that an inherent disclosure must be recognized by those of ordinary skill in the art. *See, e.g., Hyatt* v. *Boone*, 146 F.3d 1348, 1354–55, 47 USPQ2d 1128, 1132 (Fed. Cir. 1998) ("[T]he purpose of the description requirement is 'to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him.' * * * Thus, the written description must include all of the limitations of the interference count, or the applicant must show that any absent text is necessarily comprehended in the description provided *and would have been so understood* at the time the patent application was filed." (emphasis added)). *See also Reiffin* v. *Microsoft Corp.*, 214 F.3d 1342, 1346, 54 USPQ2d 1915, 1917 (Fed. Cir. 2000) (The "application considered as a whole must convey to one of ordinary skill in the art, either explicitly or inherently, that [the inventor] invented the subject matter claimed * * *. See * * * *Continental Can Co. USA* v. *Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (descriptive matter may be inherently present in a specification if one skilled in the art would necessarily recognize such a disclosure)").

(27) *Comment:* Several comments pointed out an inconsistency in the Federal Register Notice re: the Revised Interim Written Description Guidelines. The inconsistency concerned the treatment of claims directed to an isolated DNA comprising SEQ ID NO:1 wherein SEQ ID NO:1 is an expressed sequence tag. The comments contrasted paragraphs 34 and 35 of the Response to

Public Comments with the statement in the text of the Guidelines that a genus must be supported by a representative number of species (as analyzed in Example 7 of the training materials). *Response:* The USPTO acknowledges that there was an inconsistency. The Office notes that a claim reciting a nucleic acid comprising SEQ ID NO:1 may be subject to a rejection for lack of an adequate written description where particular identifiable species within the scope of the claim lack an adequate written description. The training materials as amended exemplify an appropriate analysis.

(28) *Comment:* One comment stated that the USPTO should respond to the issue of whether the U.S. is meeting its TRIPs obligations. This comment noted that the USPTO did not address an earlier comment regarding the "Interim Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, ¶ 1, 'Written Description' Requirement," 63 FR 32,639, June 15, 1998, which questioned whether the written description requirement is truly different from the enablement requirement, and indicated that such a requirement may be contrary to the TRIPs provisions of the World Trade Organization (Article 27.1). Article 27.1 requires WTO Members to, *inter alia*, make patents available, with limited exceptions, for products and processes in all fields of technology so long as those products and processes are new, involve an inventive step, and are capable of industrial application. The comment further suggested a response. *Response:* TRIPs Article 27 does not address what must be included in a patent application to allow WTO Member officials to determine whether particular inventions meet the standards for patentability established in that Article. TRIPs Article 29, which is more relevant to this comment, states that Members "shall require" patent applicants to disclose their invention "in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art." If the written description is not clear and complete, the applicant may not have been in possession of the invention. This may support both written description and enablement standards. In addition, Article 29 expressly authorizes Members to require patent applicants to disclose the best method the inventor knows at the time of filing an application for carrying out the invention.

(29) *Comment:* Two comments commended the USPTO for eliminating the Biotechnology Specific Examples in the Revised Interim Written Description Guidelines and providing separate training materials. One comment indicated a need to reconfirm the examples set forth in the Interim Written Description Guidelines published in 1998. *Response:* The current training materials reflect the manner in which the USPTO interprets the Written Description Guidelines.

(30) *Comment:* Several comments addressed specific concerns about the examiner training materials. *Response:* The comments received with respect to the training materials will be taken under advisement as the Office revises the training materials in view of the revisions to the Guidelines. The specific comments will not be addressed herein as they do not impact the language of the Guidelines.

Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement

These "Written Description Guidelines" are intended to assist Office personnel in the examination of patent applications for compliance with the written description requirement of 35 U.S.C. 112, ¶ 1. This revision is based on the Office's current understanding of the law and public comments received in response to the USPTO's previous request for public comments on its Revised Interim Written Description Guidelines and is believed to be fully consistent with binding precedent of the U.S. Supreme Court, as well as the U.S. Court of Appeals for the Federal Circuit and its predecessor courts.

This revision does not constitute substantive rulemaking and hence does not have the force and effect of law. It is designed to assist Office personnel in analyzing claimed subject matter for compliance with substantive law. Rejections will be based upon the substantive law, and it is these rejections which are appealable. Consequently, any perceived failure by Office personnel to follow these Guidelines is neither appealable nor petitionable.

These Guidelines are intended to form part of the normal examination process. Thus, where Office personnel establish a *prima facie* case of lack of written description for a claim, a thorough review of the prior art and examination on the merits for compliance with the other statutory requirements, including those of 35 U.S.C. 101, 102, 103, and 112, is to be conducted prior to completing an Office action which includes a rejection for lack of written description. Office personnel are to rely on this revision of the Guidelines in the event of any inconsistent treatment of issues involving the written description requirement between these Guidelines and any earlier guidance provided from the Office.

I. General Principles Governing Compliance With the "Written Description" Requirement for Applications

The first paragraph of 35 U.S.C. 112 requires that the "specification shall contain a written description of the invention * * *." This requirement is separate and distinct from the enablement requirement.[1] The written description requirement has several policy objectives. "[T]he 'essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed."[2] Another objective is to put the public in possession of what the applicant claims as the invention.[3] The written description requirement of the Patent Act promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent's term.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.[4] An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention.[5] Possession may be shown in a variety of ways including description of an actual reduction to practice,[6] or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete,[7] or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.[8] A question as to whether a specification provides an adequate written description may arise in the context of an original claim which is not described sufficiently, a new or amended claim wherein a claim limitation has been added or removed, or a claim to entitlement of an earlier priority date or effective filing date under 35 U.S.C. 119, 120, or 365(c).[9] Compliance with the written description requirement is a question of

fact which must be resolved on a case-by-case basis.[10]

A. Original Claims

There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed.[11] However, the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention.[12] The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art.[13] This problem may arise where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function.[14] A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process.[15]

B. New or Amended Claims

The proscription against the introduction of new matter in a patent application[16] serves to prevent an applicant from adding information that goes beyond the subject matter originally filed.[17] Thus, the written description requirement prevents an applicant from claiming subject matter that was not adequately described in the specification as filed. New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement.[18] While there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure. An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also recognize the appropriate correction.[19] Deposits made after the application filing date cannot be relied upon to support additions to or correction of information in the application as filed.[20]

Under certain circumstances, omission of a limitation can raise an issue regarding whether the inventor had possession of a broader, more generic invention.[21] A claim that omits an element which applicant describes as an essential or critical feature of the invention originally disclosed does not comply with the written description requirement.[22]

The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed.[23]

II. Methodology for Determining Adequacy of Written Description

A. Read and Analyze the Specification for Compliance With 35 U.S.C. 112, ¶1

Office personnel should adhere to the following procedures when reviewing patent applications for compliance with the written description requirement of 35 U.S.C. 112, ¶1. The examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims. There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed;[24] however, with respect to newly added or amended claims, applicant should show support in the original disclosure for the new or amended claims.[25] Consequently, rejection of an original claim for lack of written description should be rare. The inquiry into whether the description requirement is met is a question of fact that must be determined on a case-by-case basis.[26]

1. For Each Claim, Determine What the Claim as a Whole Covers

Claim construction is an essential part of the examination process. Each claim must be separately analyzed and given its broadest reasonable interpretation in light of and consistent with the written description.[27] The entire claim must be considered, including the preamble language[28] and the transitional phrase.[29] The claim as a whole, including all limitations found in the preamble,[30] the transitional phrase, and the body of the claim, must be sufficiently supported to satisfy the written description requirement.[31]

The examiner should evaluate each claim to determine if sufficient structures, acts, or functions are recited to make clear the scope and meaning of the claim, including the weight to be given the preamble.[32] The absence of definitions or details for well-established terms or procedures should not be the basis of a rejection under 35 U.S.C. 112, ¶1, for lack of adequate written description. Limitations may not, however, be imported into the claims from the specification.

2. Review the Entire Application to Understand How Applicant Provides Support for the Claimed Invention Including Each Element and/or Step

Prior to determining whether the disclosure satisfies the written description requirement for the claimed subject matter, the examiner should review the claims and the entire specification, including the specific embodiments, figures, and sequence listings, to understand how applicant provides support for the various features of the claimed invention.[33] The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention. Such a review is conducted from the standpoint of one of skill in the art at the time the application was filed[34] and should include a determination of the field of the invention and the level of skill and knowledge in the art. Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement. Information which is well known in the art need not be described in detail in the specification.[35]

3. Determine Whether There is Sufficient Written Description to Inform a Skilled Artisan That Applicant was in Possession of the Claimed Invention as a Whole at the Time the Application Was Filed

a. Original claims. Possession may be shown in many ways. For example, possession may be shown, *inter alia*, by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention.[36]

A specification may describe an actual reduction to practice by showing

that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose.[37] Description of an actual reduction to practice of a biological material may be shown by specifically describing a deposit made in accordance with the requirements of 37 CFR 1.801 *et seq.*[38]

An applicant may show possession of an invention by disclosure of drawings[39] or structural chemical formulas[40] that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. The description need only describe in detail that which is new or not conventional.[41] This is equally true whether the claimed invention is directed to a product or a process.

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics[42] which provide evidence that applicant was in possession of the claimed invention,[43] *i.e.*, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.[44] What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail.[45] If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met.[46]

(1) For each claim drawn to a single embodiment or species:[47]

(a) Determine whether the application describes an actual reduction to practice of the claimed invention.

(b) If the application does not describe an actual reduction to practice, determine whether the invention is complete as evidenced by a reduction to drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole.

(c) If the application does not describe an actual reduction to practice or reduction to drawings or structural chemical formula as discussed above, determine whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention.

(i) Determine whether the application as filed describes the complete structure (or acts of a process) of the claimed invention as a whole. The complete structure of a species or embodiment typically satisfies the requirement that the description be set forth "in such full, clear, concise, and exact terms" to show possession of the claimed invention.[48] If a complete structure is disclosed, the written description requirement is satisfied for that species or embodiment, and a rejection under 35 U.S.C. 112, ¶ 1, for lack of written description must not be made.

(ii) If the application as filed does not disclose the complete structure (or acts of a process) of the claimed invention as a whole, determine whether the specification discloses other relevant identifying characteristics sufficient to describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention.[49]

Whether the specification shows that applicant was in possession of the claimed invention is not a single, simple determination, but rather is a factual determination reached by considering a number of factors. Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient.[50] Patents and printed publications in the art should be relied upon to determine whether an art is mature and what the level of knowledge and skill is in the art. In most technologies which are mature, and wherein the knowledge and level of skill in the art is high, a written description question should not be raised for original claims even if the specification discloses only a method of making the invention and the function of the invention.[51] In contrast, for inventions in emerging and unpredictable technologies, or for inventions characterized by factors not reasonably predictable which are known to one of ordinary skill in the art, more evidence is required to show possession. For example, disclosure of only a method of making the invention and the function may not be sufficient to support a product claim other than a product-by-process claim.[52] Furthermore, disclosure of a partial structure without additional characterization of the product may not be sufficient to evidence possession of the claimed invention.[53]

Any claim to a species that does not meet the test described under at least one of (a), (b), or (c) must be rejected as lacking adequate written description under 35 U.S.C. 112, ¶ 1.

(2) For each claim drawn to a genus:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see (1)(a), above), reduction to drawings (see (1)(b), above), or by disclosure of relevant, identifying characteristics, *i.e.*, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see (1)(c), above).[54]

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. On the other hand, there may be situations where one species adequately supports a genus.[55] What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus.[56] Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces.[57] If a representative number of adequately described species are not disclosed for a genus, the claim to that genus must be rejected as lacking adequate written description under 35 U.S.C. 112, ¶ 1.

b. New claims, amended claims, or claims asserting entitlement to the benefit of an earlier priority date or filing date under 35 U.S.C. 119, 120, or

365(c). The examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the original disclosure a description of the invention defined by the claims.[58] However, when filing an amendment an applicant should show support in the original disclosure for new or amended claims.[59] To comply with the written description requirement of 35 U.S.C. 112, ¶ 1, or to be entitled to an earlier priority date or filing date under 35 U.S.C. 119, 120, or 365(c), each claim limitation must be expressly,[60] implicitly,[61] or inherently[62] supported in the originally filed disclosure.[63] Furthermore, each claim must include all elements which applicant has described as essential.[64]

If the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, ¶ 1, as lacking adequate written description, or in the case of a claim for priority under 35 U.S.C. 119, 120, or 365(c), the claim for priority must be denied.

III. Complete Patentability Determination Under All Statutory Requirements and Clearly Communicate Findings, Conclusions, and Their Bases

The above only describes how to determine whether the written description requirement of 35 U.S.C. 112, ¶ 1, is satisfied. Regardless of the outcome of that determination, Office personnel must complete the patentability determination under all the relevant statutory provisions of title 35 of the U.S. Code.

Once Office personnel have concluded analysis of the claimed invention under all the statutory provisions, including 35 U.S.C. 101, 112, 102, and 103, they should review all the proposed rejections and their bases to confirm their correctness. Only then should any rejection be imposed in an Office action. The Office action should clearly communicate the findings, conclusions, and reasons which support them. When possible, the Office action should offer helpful suggestions on how to overcome rejections.

A. For Each Claim Lacking Written Description Support, Reject the Claim Under Section 112, ¶ 1, for Lack of Adequate Written Description

A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption.[65] The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims.[66] In rejecting a claim, the examiner must set forth express findings of fact regarding the above analysis which support the lack of written description conclusion. These findings should:

(1) Identify the claim limitation at issue; and

(2) Establish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed. A general allegation of "unpredictability in the art" is not a sufficient reason to support a rejection for lack of adequate written description.

When appropriate, suggest amendments to the claims which can be supported by the application's written description, being mindful of the prohibition against the addition of new matter in the claims or description.[67]

B. Upon Reply by Applicant, Again Determine the Patentability of the Claimed Invention, Including Whether the Written Description Requirement Is Satisfied by Reperforming the Analysis Described Above in View of the Whole Record

Upon reply by applicant, before repeating any rejection under 35 U.S.C. 112, ¶ 1, for lack of written description, review the basis for the rejection in view of the record as a whole, including amendments, arguments, and any evidence submitted by applicant. If the whole record now demonstrates that the written description requirement is satisfied, do *not* repeat the rejection in the next Office action. If the record still does not demonstrate that the written description is adequate to support the claim(s), repeat the rejection under 35 U.S.C. 112, ¶ 1, fully respond to applicant's rebuttal arguments, and properly treat any further showings submitted by applicant in the reply. When a rejection is maintained, any affidavits relevant to the 112, ¶ 1, written description requirement,[68] must be thoroughly analyzed and discussed in the next Office action.

Dated: December 29, 2000.

Q. Todd Dickinson,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

Endnotes

[1] *See, e.g., Vas-Cath, Inc.* v. *Mahurkar*, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991).

[2] *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977).

[3] *See Regents of the University of California* v. *Eli Lilly*, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998).

[4] *See, e.g., Vas-Cath, Inc.* v. *Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. Much of the written description case law addresses whether the specification as originally filed supports claims not originally in the application. The issue raised in the cases is most often phrased as whether the original application provides "adequate support" for the claims at issue or whether the material added to the specification incorporates "new matter" in violation of 35 U.S.C. 132. The "written description" question similarly arises in the interference context, where the issue is whether the specification of one party to the interference can support the newly added claims corresponding to the count at issue, *i.e.*, whether that party can "make the claim" corresponding to the interference count. *See, e.g., Martin* v. *Mayer*, 823 F.2d 500, 503, 3 USPQ2d 1333, 1335 (Fed. Cir. 1987).

In addition, early opinions suggest the Patent and Trademark Office was unwilling to find written descriptive support when the only description was found in the claims; however, this viewpoint was rejected. *See In re Koller*, 613 F.2d 819, 204 USPQ 702 (CCPA 1980) (original claims constitute their own description); *accord In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973); *accord In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976) (accord). It is now well accepted that a satisfactory description may be in the claims or any other portion of the originally filed specification. These early opinions did not address the quality or specificity of particularity that was required in the description, *i.e.*, how much description is enough.

[5] *Lockwood* v. *American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

[6] An application specification may show actual reduction to practice by describing testing of the claimed invention or, in the case of biological materials, by specifically describing a deposit made in accordance with 37 CFR 1.801 *et seq. See also Deposit of Biological Materials for Patent Purposes, Final Rule*, 54 FR 34,864 (August 22, 1989) ("The requirement for a specific identification is consistent with the description requirement of the first paragraph of 35 U.S.C. 112, and to provide an antecedent basis for the biological material which either has been or will be deposited before the patent is granted." *Id.* at 34,876. "The description must be sufficient to permit verification that the deposited biological material is in fact that disclosed. Once the

patent issues, the description must be sufficient to aid in the resolution of questions of infringement." *Id.* at 34,880.). Such a deposit is not a substitute for a written description of the claimed invention. The written description of the deposited material needs to be as complete as possible because the examination for patentability proceeds solely on the basis of the written description. *See, e.g., In re Lundak*, 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985). *See also* 54 FR at 34,880 ("As a general rule, the more information that is provided about a particular deposited biological material, the better the examiner will be able to compare the identity and characteristics of the deposited biological material with the prior art.").

[7] *Pfaff* v. *Wells Electronics, Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

[8] *See Amgen, Inc.* v. *Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

[9] A description requirement issue can arise for original claims (*see, e.g., Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398) as well as new or amended claims. Most typically, the issue will arise in the context of determining whether new or amended claims are supported by the description of the invention in the application as filed (*see, e.g., In re Wright*, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989)), whether a claimed invention is entitled to the benefit of an earlier priority date or effective filing date under 35 U.S.C. 119, 120, or 365(c) (*see, e.g., Tronzo* v. *Biomet, Inc.*, 156 F.3d 1154, 47 USPQ2d 1829 (Fed. Cir. 1998); *Fiers* v. *Revel*, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993); *In re Ziegler*, 992 F.2d 1197, 1200, 26 USPQ2d 1600, 1603 (Fed. Cir. 1993)), or whether a specification provides support for a claim corresponding to a count in an interference (*see, e.g., Fields* v. *Conover*, 443 F.2d 1386, 170 USPQ 276 (CCPA 1971)).

[10] *Vas-Cath, Inc.* v. *Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991).

[11] *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims").

[12] See endnote 4.

[13] For example, consider the claim "A gene comprising SEQ ID NO:1." A determination of what the claim as a whole covers may result in a conclusion that specific structures such as a promoter, a coding region, or other elements are included. Although all genes encompassed by this claim share the characteristic of comprising SEQ ID NO:1, there may be insufficient description of those specific structures (*e.g.*, promoters, enhancers, coding regions, and other regulatory elements) which are also included.

[14] A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. For example, even though a genetic code table would correlate a known amino acid sequence with a genus of coding nucleic acids, the same table cannot predict the native, naturally occurring nucleic acid sequence of a naturally occurring mRNA or its corresponding cDNA. *Cf. In re Bell*, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993), and *In re Deuel*, 51 F.3d 1552, 34 USPQ2d 1210 (Fed. Cir. 1995) (holding that a process could not render the product of that process obvious under 35 U.S.C. 103). The Federal Circuit has pointed out that under United States law, a description that does not render a claimed invention obvious cannot sufficiently describe the invention for the purposes of the written description requirement of 35 U.S.C. 112. *Eli Lilly*, 119 F.3d at 1567, 43 USPQ2d at 1405.

Compare Fonar Corp. v. *General Electric Co.*, 107 F.3d 1543, 1549, 41 USPQ2d 1801, 1805 (Fed. Cir. 1997) ("As a general rule, where software constitutes part of a best mode of carrying out an invention, description of such a best mode is satisfied by a disclosure of the functions of the software. This is because, normally, writing code for such software is within the skill of the art, not requiring undue experimentation, once its functions have been disclosed. * * * Thus, flow charts or source code listings are not a requirement for adequately disclosing the functions of software.").

[15] *See, e.g., Fujikawa* v. *Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); *In re Ruschig*, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967) ("*If* n-propylamine had been used in making the compound instead of n-butylamine, the compound of claim 13 would have resulted. Appellants submit to us, as they did to the board, an imaginary specific example patterned on specific example 6 by which the above butyl compound is made so that we can see what a simple change would have resulted in a specific supporting disclosure being present in the present specification. The trouble is that there is no such disclosure, easy though it is to imagine it.") (emphasis in original); *Purdue Pharma L.P.* v. *Faulding Inc.*, 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000) ("the specification does not clearly disclose to the skilled artisan that the inventors * * * considered the [] ratio to be part of their invention * * *. There is therefore no force to Purdue's argument that the written description requirement was satisfied because the disclosure revealed a broad invention from which the [later-filed] claims carved out a patentable portion").

[16] 35 U.S.C. §§ 132 and 251. *See also In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981). *See* Manual of Patent Examining Procedure (MPEP) §§ 2163.06–2163.07 (7th Ed., Rev. 1, Feb. 2000) for a more detailed discussion of the written description requirement and its relationship to new matter.

[17] The claims as filed in the original specification are part of the disclosure and, therefore, if an application as originally filed contains a claim disclosing material not found in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. *In re Benno*, 768 F.2d 1340, 226 USPQ 683 (Fed. Cir. 1985).

[18] *See, e.g., In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads).

[19] *In re Oda*, 443 F.2d 1200, 170 USPQ 260 (CCPA 1971). With respect to the correction of sequencing errors in applications disclosing nucleic acid and/or amino acid sequences, it is well known that sequencing errors are a common problem in molecular biology. *See, e.g.*, Peter Richterich, *Estimation of Errors in 'Raw' DNA Sequences: A Validation Study*, 8 Genome Research 251–59 (1998). If an application as filed includes sequence information and references a deposit of the sequenced material made in accordance with the requirements of 37 CFR § 1.801 *et seq.*, amendment may be permissible.

[20] Corrections of minor errors in the sequence may be possible based on the argument that one of skill in the art would have resequenced the deposited material and would have immediately recognized the minor error. Deposits made after the filing date can only be relied upon to provide support for the correction of sequence information if applicant submits a statement in compliance with 37 CFR § 1.804 stating that the biological material which is deposited is a biological material specifically defined in the application as filed.

[21] *See, e.g., Gentry Gallery, Inc.* v. *Berkline Corp.*, 134 F.3d 1473, 45 USPQ2d 1498 (Fed. Cir. 1998) (claims to a sectional sofa comprising, *inter alia*, a console and a control means were held invalid for failing to satisfy the written description requirement where the claims were broadened by removing the location of the control means.); *Johnson Worldwide Associates* v. *Zebco Corp.*, 175 F.3d 985, 993, 50 USPQ2d 1607, 1613 (Fed. Cir. 1999) (In *Gentry Gallery*, the "court's determination that the patent disclosure did not support a broad meaning for the disputed claim terms was premised on clear statements in the written description that described the location of a claim element—the 'control means'—as 'the only possible location' and that variations were 'outside the stated purpose of the invention.' *Gentry Gallery*, 134 F.3d at 1479, 45 USPQ2d at 1503. *Gentry Gallery*, then, considers the situation where the patent's disclosure makes crystal clear that a particular (*i.e.*, narrow) understanding of a claim term is an 'essential element of [the inventor's] invention.' "); *Tronzo* v. *Biomet*, 156 F.3d at 1158–59, 47 USPQ2d at 1833 (Fed. Cir. 1998) (claims to generic cup shape were not entitled to filing date of parent application which disclosed "conical cup" in view of the disclosure of the

parent application stating the advantages and importance of the conical shape.).

[22] *See Gentry Gallery*, 134 F.3d at 1480, 45 USPQ2d at 1503; *In re Sus*, 306 F.2d 494, 504, 134 USPQ 301, 309 (CCPA 1962) ("[O]ne skilled in this art would not be taught by the written description of the invention in the specification that any 'aryl or substituted aryl radical' would be suitable for the purposes of the invention but rather that only *certain aryl radicals* and certain specifically substituted aryl radicals [*i.e.*, aryl azides] would be suitable for such purposes.") (emphasis in original). A claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may also be subject to rejection under 35 U.S.C. 112, ¶ 1, as not enabling, or under 35 U.S.C. 112, ¶ 2. *See In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976); *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976); and *In re Collier*, 397 F.2d 1003, 158 USPQ 266 (CCPA 1968). *See also* MPEP § 2172.01.

[23] *See, e.g., Vas-Cath, Inc.*, 935 F.2d at 1563–64, 19 USPQ2d at 1117.

[24] *Wertheim*, 541 F.2d at 262, 191 USPQ at 96.

[25] *See* MPEP §§ 714.02 and 2163.06 ("Applicant should * * * specifically point out the support for any amendments made to the disclosure."); and MPEP § 2163.04 ("If applicant amends the claims and points out where and/or how the originally filed disclosure supports the amendment(s), and the examiner finds that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of the filing of the application, the examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.").

[26] *See In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) ("Precisely how close [to the claimed invention] the description must come to comply with § 112 must be left to case-by-case development."); *In re Wertheim*, 541 F.2d at 262, 191 USPQ at 96 (inquiry is primarily factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure).

[27] *See, e.g., In re Morris*, 127 F.3d 1048, 1053–54, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997).

[28] "Preamble language" is that language in a claim appearing before the transitional phase, *e.g.*, before "comprising," "consisting essentially of," or "consisting of."

[29] The transitional term "comprising" (and other comparable terms, *e.g.*, "containing," "including," and "having") is "open-ended—it covers the expressly recited subject matter, alone or in combination with unrecited subject matter. *See, e.g., Genentech, Inc.* v. *Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) (" 'Comprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim."); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves the "claim open for the inclusion of unspecified ingredients even in major amounts"). "By using the term 'consisting essentially of,' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. A 'consisting essentially of' claim occupies a middle ground between closed claims that are written in a 'consisting of' format and fully open claims that are drafted in a 'comprising' format." *PPG Industries* v. *Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353–54 (Fed. Cir. 1998). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, 'consisting essentially of' will be construed as equivalent to "comprising." *See, e.g., PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase "consisting essentially of" for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). *See also In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 895–96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

[30] *See Pac-Tec Inc.* v. *Amerace Corp.*, 903 F.2d 796, 801, 14 USPQ2d 1871, 1876 (Fed. Cir. 1990) (determining that preamble language that constitutes a structural limitation is actually part of the claimed invention).

[31] An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

[32] *See, e.g., Bell Communications Research, Inc.* v. *Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995) ("[A] claim preamble has the import that the claim as a whole suggests for it."); *Corning Glass Works* v. *Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989) (The determination of whether preamble recitations are structural limitations can be resolved only on review of the entirety of the application "to gain an understanding of what the inventors actually invented and intended to encompass by the claim.").

[33] An element may be critical where those of skill in the art would require it to determine that applicant was in possession of the invention. *Compare Rasmussen*, 650 F.2d at 1215, 211 USPQ at 327 ("one skilled in the art who read Rasmussen's specification would understand that it is unimportant *how* the layers are adhered, so long as they are adhered") (emphasis in original), *with Amgen, Inc.* v. *Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) ("it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it").

[34] *See, e.g., Wang Labs.* v. *Toshiba Corp.*, 993 F.2d 858, 865, 26 USPQ2d 1767, 1774 (Fed. Cir. 1993).

[35] *See, e.g., Hybritech, Inc.* v. *Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379–80, 231 USPQ 81, 90 (Fed. Cir. 1986).

[36] *See, e.g., Purdue Pharma L.P.* v. *Faulding Inc.*, 230 F.3d 1320, ___, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000) (the written description "inquiry is a factual one and must be assessed on a case-by-case basis"); *see also Pfaff* v. *Wells Electronics, Inc.*, 55 U.S. at 66, 119 S.Ct. at 311, 48 USPQ2d at 1646 ("The word 'invention' must refer to a concept that is complete, rather than merely one that is 'substantially complete.' It is true that reduction to practice ordinarily provides the best evidence that an invention is complete. But just because reduction to practice is sufficient evidence of completion, it does not follow that proof of reduction to practice is necessary in every case. Indeed, both the facts of the *Telephone Cases* and the facts of this case demonstrate that one can prove that an invention is complete and ready for patenting before it has actually been reduced to practice.").

[37] *Cooper* v. *Goldfarb*, 154 F.3d 1321, 1327, 47 USPQ2d 1896, 1901 (Fed. Cir. 1998). *See also UMC Elecs. Co.* v. *United States*, 816 F.2d 647, 652, 2 USPQ2d 1465, 1468 (Fed. Cir. 1987) ("[T]here cannot be a reduction to practice of the invention * * * without a physical embodiment which includes all limitations of the claim."); *Estee Lauder Inc.* v. *L'Oreal, S.A.*, 129 F.3d 588, 593, 44 USPQ2d 1610, 1614 (Fed. Cir. 1997) ("[A] reduction to practice does not occur until the inventor has determined that the invention will work for its intended purpose."); *Mahurkar* v. *C.R. Bard, Inc.*, 79 F.3d 1572, 1578, 38 USPQ2d 1288, 1291 (Fed. Cir. 1996) (determining that the invention will work for its intended purpose may require testing depending on the character of the invention and the problem it solves).

[38] 37 CFR 1.804, 1.809. *See also* endnote 6.

[39] *See, e.g., Vas-Cath*, 935 F.2d at 1565, 19 USPQ2d at 1118 ("drawings alone may provide a 'written description' of an invention as required by § 112"); *In re Wolfensperger*, 302 F.2d 950, 133 USPQ 537 (CCPA 1962) (the drawings of applicant's specification provided sufficient written descriptive support for the claim limitation at issue); *Autogiro Co. of America* v. *United States*, 384 F.2d 391, 398, 155 USPQ 697, 703 (Ct. Cl. 1967) ("In those instances where a visual representation can flesh out words, drawings may be used in the same manner and with the same limitations as the specification.").

[40] *See, e.g., Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406 ("In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus.").

[41] *See Hybritech* v. *Monoclonal Antibodies*, 802 F.2d at 1384, 231 USPQ at 94; *Fonar Corp.* v. *General Electric Co.*, 107 F.3d at 1549, 41 USPQ2d at 1805 (source code description not required).

[42] For example, the presence of a restriction enzyme map of a gene may be relevant to a statement that the gene has been isolated. One skilled in the art may be able to determine when the gene disclosed is the same as or different from a gene isolated by another by comparing the restriction enzyme map. In contrast, evidence that the gene could be digested with a nuclease would not normally represent a relevant characteristic since any gene would be digested with a nuclease. Similarly, isolation of an mRNA and its expression to produce the protein of interest is strong evidence of possession of an mRNA for the protein.

For some biomolecules, examples of identifying characteristics include a sequence, structure, binding affinity, binding specificity, molecular weight, and length. Although structural formulas provide a convenient method of demonstrating possession of specific molecules, other identifying characteristics or combinations of characteristics may demonstrate the requisite possession. For example, unique cleavage by particular enzymes, isoelectric points of fragments, detailed restriction enzyme maps, a comparison of enzymatic activities, or antibody cross-reactivity may be sufficient to show possession of the claimed invention to one of skill in the art. *See Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966 ("written description" requirement may be satisfied by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention").

[43] A definition by function alone "does not suffice" to sufficiently describe a coding sequence "because it is only an indication of what the gene does, rather than what it is." *Eli Lilly*, 119 F.3 at 1568, 43 USPQ2d at 1406. *See also Fiers*, 984 F.2d at 1169–71, 25 USPQ2d at 1605–06 (discussing *Amgen Inc.* v. *Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991)).

[44] If a claim limitation invokes 35 U.S.C. 112, ¶ 6, it must be interpreted to cover the corresponding structure, materials, or acts in the specification and "equivalents thereof." *See* 35 U.S.C. 112, ¶ 6. *See also B. Braun Medical, Inc.* v. *Abbott Lab.*, 124 F.3d 1419, 1424, 43 USPQ2d 1896, 1899 (Fed. Cir. 1997). In considering whether there is 35 U.S.C. 112, ¶ 1, support for a means- (or step) plus-function claim limitation, the examiner must consider not only the original disclosure contained in the summary and detailed description of the invention portions of the specification, but also the original claims, abstract, and drawings. A means- (or step-) plus-function claim limitation is adequately described under 35 U.S.C. 112, ¶ 1, if: (1) The written description adequately links or associates adequately described particular structure, material, or acts to the function recited in a means- (or step-) plus-function claim limitation; or (2) it is clear based on the facts of the application that one skilled in the art would have known what structure, material, or acts perform the function recited in a means- (or step-) plus-function limitation. Note also: A rejection under 35 U.S.C. 112, ¶ 2, "cannot stand where there is adequate description in the specification to satisfy 35 U.S.C. 112, first paragraph, regarding means-plus-function recitations that are not, per se, challenged for being unclear." *In re Noll*, 545 F.2d 141, 149, 191 USPQ 721, 727 (CCPA 1976). *See Supplemental Examination Guidelines for Determining the Applicability of 35 U.S.C. 112, ¶ 6*, 65 FR 38510, June 21, 2000.

[45] *See Hybritech Inc.* v. *Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94.

[46] *See, e.g., Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin* v. *Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in *ipsis verbis* [*i.e.*, "in the same words"] to be sufficient").

[47] A claim which is limited to a single disclosed embodiment or species is analyzed as a claim drawn to a single embodiment or species, whereas a claim which encompasses two or more embodiments or species within the scope of the claim is analyzed as a claim drawn to a genus. *See also* MPEP § 806.04(e).

[48] 35 U.S.C. 112, ¶ 1. *Cf. Fields* v. *Conover*, 443 F.2d 1386, 1392, 170 USPQ 276, 280 (CCPA 1971) (finding a lack of written description because the specification lacked the "full, clear, concise, and exact written description" which is necessary to support the claimed invention).

[49] For example, if the art has established a strong correlation between structure and function, one skilled in the art would be able to predict with a reasonable degree of confidence the structure of the claimed invention from a recitation of its function. Thus, the written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. In contrast, without such a correlation, the capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely. In this latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. *See Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406 (written description requirement not satisfied by merely providing "a result that one might achieve if one made that invention"); *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372–73 (Fed. Cir. 1984) (affirming a rejection for lack of written description because the specification does "little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate"). *Compare Fonar*, 107 F.3d at 1549, 41 USPQ2d at 1805 (disclosure of software function adequate in that art).

[50] *See Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

[51] *See, e.g., In re Hayes Microcomputer Products, Inc. Patent Litigation*, 982 F.2d 1527, 1534–35, 25 USPQ2d 1241, 1246 (Fed. Cir. 1992) ("One skilled in the art would know how to program a microprocessor to perform the necessary steps described in the specification. Thus, an inventor is not required to describe every detail of his invention. An applicant's disclosure obligation varies according to the art to which the invention pertains. Disclosing a microprocessor capable of performing certain functions is sufficient to satisfy the requirement of section 112, first paragraph, when one skilled in the relevant art would understand what is intended and know how to carry it out.")

[52] *See, e.g., Fiers* v. *Revel*, 984 F.2d at 1169, 25 USPQ2d at 1605; *Amgen.*, 927 F.2d at 1206, 18 USPQ2d at1021. Where the process has actually been used to produce the product, the written description requirement for a product-by-process claim is clearly satisfied; however, the requirement may not be satisfied where it is not clear that the acts set forth in the specification can be performed, or that the product is produced by that process.

[53] *See, e.g., Amgen*, 927 F.2d at1206, 18 USPQ2d at 1021 ("A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it. Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, *i.e.*, until after the gene has been isolated.") (citations omitted). In such instances the alleged conception fails not merely because the field is unpredictable or because of the general uncertainty surrounding experimental sciences, but because the conception is incomplete due to factual uncertainty that undermines the specificity of the inventor's idea of the invention. *Burroughs Wellcome Co.* v. *Barr Laboratories Inc.*, 40 F.3d 1223, 1229, 32 USPQ2d 1915, 1920 (Fed. Cir. 1994). Reduction to practice in effect provides the only evidence to corroborate conception (and therefore possession) of the invention. *Id.*

[54] *See Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

[55] *See, e.g., Rasmussen*, 650 F.2d at 1214, 211 USPQ at 326–27 (disclosure of a single method of adheringly applying one layer to another was sufficient to support a generic claim to "adheringly applying" because one skilled in the art reading the specification would understand that it is unimportant how the layers are adhered, so long as they are adhered); *In re Herschler*, 591 F.2d 693, 697, 200 USPQ 711, 714 (CCPA 1979) (disclosure of corticosteriod in DMSO sufficient to support claims drawn to a method of using a mixture of a "physiologically active steroid" and DMSO because "use of known chemical compounds in a manner auxiliary

to the invention must have a corresponding written description only so specific as to lead one having ordinary skill in the art to that class of compounds. Occasionally, a functional recitation of those known compounds in the specification may be sufficient as that description."); *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 285 (CCPA 1973) (the phrase "air or other gas which is inert to the liquid" was sufficient to support a claim to "inert fluid media" because the description of the properties and functions of the air or other gas segmentizing medium would suggest to a person skilled in the art that appellant's invention includes the use of "inert fluid" broadly.). However, in *Tronzo* v. *Biomet*, 156 F.3d at 1159, 47 USPQ2d at1833 (Fed. Cir. 1998), the disclosure of a species in the parent application did not suffice to provide written description support for the genus in the child application.

[56] *See, e.g., Eli Lilly.*

[57] For example, in the molecular biology arts, if an applicant disclosed an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence, but not necessarily any particular species. *Cf. In re Bell*, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994).

[58] *See Wertheim*, 541 F.2d at 263, 191 USPQ at 97 ("[T]he PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.").

[59] *See* MPEP §§ 714.02 and 2163.06 ("Applicant should * * * specifically point out the support for any amendments made to the disclosure.").

[60] *See, e.g., In re Wright*, 866 F.2d 422, 425, 9 USPQ2d 1649, 1651 (Fed. Cir. 1989) (Original specification for method of forming images using photosensitive microcapsules which describes removal of microcapsules from surface and warns that capsules not be disturbed prior to formation of image, unequivocally teaches absence of permanently fixed microcapsules and supports amended language of claims requiring that microcapsules be "not permanently fixed" to underlying surface, and therefore meets description requirement of 35 U.S.C. 112.).

[61] *See, e.g., In re Robins*, 429 F.2d 452, 456–57, 166 USPQ 552, 555 (CCPA 1970) ("[W]here no explicit description of a generic invention is to be found in the specification * * * mention of representative compounds may provide an implicit description upon which to base generic claim language."); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily implicitly described by a genus encompassing it and a species upon which it reads).

[62] *See, e.g., In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950–51 (Fed. Cir. 1999) ("To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'") (citations omitted).

[63] When an explicit limitation in a claim "is not present in the written description whose benefit is sought it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation." *Hyatt* v. *Boone*, 146 F.3d 1348, 1353, 47 USPQ2d 1128, 1131 (Fed. Cir. 1998).

[64] *See, e.g., Johnson Worldwide Associates Inc.* v. *Zebco Corp.*, 175 F.3d at 993, 50 USPQ2d at 1613; *Gentry Gallery, Inc.* v. *Berkline Corp.*, 134 F.3d at 1479, 45 USPQ2d at 1503; *Tronzo* v. *Biomet*, 156 F.3d at 1159, 47 USPQ2d at 1833.

[65] *See, e.g., In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971).

[66] *Wertheim*, 541 F.2d at 263, 191 USPQ at 97.

[67] *See Rasmussen*, 650 F.2d at 1214, 211 USPQ at 326.

[68] *See In re Alton*, 76 F.3d 1168, 1176, 37 USPQ2d 1578, 1584 (Fed. Cir. 1996).

[FR Doc. 01–323 Filed 1–4–01; 8:45 am]
BILLING CODE 3510–16–U

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Revision of Currently Approved Information Collection; Comment Request

AGENCY: Corporation for National and Community Service

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (hereinafter "Corporation"), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirement on respondents can be properly assessed.

Currently, the Corporation is soliciting comments concerning the proposed revision of its Voucher and Payment Request Form (OMB #3045–0014).

Copies of the forms can be obtained by contacting the office listed below in the address section of this notice.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section by March 6, 2001.

ADDRESSES: Send comments to Levon Buller, National Service Trust, Corporation for National and Community Service, 1201 New York Ave., NW., Washington, DC 20525.

FOR FURTHER INFORMATION CONTACT: Levon Buller, (202) 606–5000, ext. 383.

SUPPLEMENTARY INFORMATION: The Corporation is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Corporation, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

Background

The Corporation supports programs that provide opportunities for individuals who want to become involved in national service. The service opportunities cover a wide range of activities over varying periods of time. Upon successfully completing an agreed-upon term of service in an approved AmeriCorps program, a national service participant—an AmeriCorps member—receives an "education award". This award is an amount of money set aside in the member's name in the National Service Trust Fund. This education award can be used to make payments towards qualified student loan or pay for educational expenses at qualified post-secondary institutions and approved school-to-work opportunities programs. Members have seven years in which to draw against any unused balance.

The National Service Trust is the office within the Corporation that administers the education award

United States Court of Customs and Patent Appeals.

In the Matter of the APPLICATION OF Patrick R. DRISCOLL.

Patent Appeal No. 77-560.

Oct. 6, 1977.

A decision of the Patent and Trademark Office Board of Appeals affirmed rejection of claim 13 of an application, serial no. 316,794, for "5-Substituted Thiadiazole Ureas and Their Use as Herbicides." Applicant appealed. The Court of Customs and Patent Appeals, Almond, Senior Judge, held that: (1) an earlier filed application reasonably conveyed information that, as of filing date thereof, applicant had possession of a class of 5-alkylsulfonyl-1, 3, 4-thiadiazole ureas defined in claim 13, and the applicant was entitled to the earlier filing date, and (2) failure to file terminal disclaimer in one application did not justify denial of claim on appeal, which was subject to terminal disclaimer.

Reversed.

West Headnotes

[1] Patents ⚿104
291k104

In determining whether disclosure of patent application described subject matter of subsequent claim, for which the earlier filing date was claimed, court was required to view disclosure of earlier filed application as would person skilled in art and determine whether it reasonably conveyed information that as of filing date thereof applicant had possession of the class of compounds defined in the subsequent claim. 35 U.S.C.A. §§ 102, 112, 120; Patent Office Practice Rules, rule 78(b), 35 U.S.C.A. App.

[2] Patents ⚿90(1)
291k90(1)

[2] Patents ⚿104
291k104

Earlier filed application reasonably conveyed information that, as of filing date thereof, applicant had possession of class of 5-Alkylsulfonyl-1, 3, 4-Thiadiazole Ureas defined in claim of subsequent patent application for "5- Substituted Thiadiazole Ureas and Their Use as Herbicides", and applicant was entitled to the earlier filing date. 35 U.S.C.A. §§ 102, 120.

[3] Patents ⚿120
291k120

Doctrine of rejecting "obvious" type "double patenting" is judicially created doctrine grounded in public policy rather than statute and is primarily intended to prevent prolongation of monopoly by prohibiting claims in second patent not patentably distinguishable from claims of first patent. 35 U.S.C.A. §§ 101, 102, 253.

[4] Patents ⚿120
291k120

[4] Patents ⚿156
291k156

Failure to file terminal disclaimer in previous application did not justify denial of claim on appeal; if claim on appeal should go to issue during pendency of such first-mentioned application, and latter contained potentially conflicting claims, proper procedure would be, at such time, to reject those claims for double patenting over claim of instant application, which was subject to terminal disclaimer. 35 U.S.C.A. §§ 101, 102, 253.

***1246** Michael G. Gilman, New York City, attorney of record, for appellant.

Joseph F. Nakamura, Washington, D. C., for the Commissioner of Patents, Jack E. Armore, Washington, D. C., of counsel.

Before MARKEY, Chief Judge, and RICH, BALDWIN, MILLER, Judges, and ALMOND, Senior Judge.

ALMOND, Senior Judge.

This is an appeal from the decision of the Patent and Trademark Office (PTO) Board of Appeals (board) affirming the rejection of claim 13 of appellant's application, serial No. 316,794, filed December 20, 1972, for "5-Substituted Thiadiazole Ureas and Their Use as Herbicides." [FN1] We reverse.

FN1. Mobil Oil Corp. is the real party in interest.

The Invention

The invention relates to 5-alkylsulfonyl-1, 3, 4-thiadiazole ureas which are useful in controlling undesired plant growth.

The appealed claim (paragraphing supplied) reads:

13. A Compound of the Formula

Image 1 (1▒ X 2.5▒) Available for Offline Print

wherein R is alkylsulfonyl (C 1-C 6);
R 1 is selected from the group consisting of H, alkyl (C 1-C 4), and cycloalkyl (C 3-C 6);
R 2 is from the group consisting of H, alkyl (C 1-C 4), haloalkyl (C 1-C 4), alkoxy (C 1-C 4), alkenyl (C 2-C 4), alkynyl (C 2-C 4), aryl, and haloaryl, and wherein R 1 and R 2 are alkylene which, together with N, form a ring of at least 3, but not more than 6 members;
R 3 is H or alkyl (C 1-6); and X is selected from the group consisting of oxygen and sulfur.

Background

Pursuant to 35 U.S.C. s 120,[FN2] appellant has claimed the benefit of an earlier filing ***1247** date based on a series of previously filed applications, the present application being designated a continuation-in-part of application serial No. 113,679, filed February 8, 1971 (S.N. 113,679) which is a continuation-in-part of application serial No. 818,078, filed April 21, 1969, which, in turn, is a continuation-in-part of application serial No. 782,756, filed December 10, 1968 (S.N. 782,756).[FN3]

FN2. Section 120 provides:
An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States by the same inventor shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.
The first paragraph of section 112 provides:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

FN3. The "genealogy" of the present application can be traced through additional earlier filed applications, the disclosures of which are irrelevant to the present controversy.

S.N. 782,756 contains the following disclosure relied on by appellant to support his claim under s 120:

In accordance with the invention, there is provided a compound of the formula (paragraphing supplied):

Image 2 (1.25▒ X 2.5▒) Available for Offline Print

wherein R is selected from the group consisting of H, alkyl (C 1-C 6), haloalkyl (C 1-C 6), cycloalkyl (C 3-C 6), halocycloalkyl (C 3-C 6), alkoxy, alkoxyalkyl, alkoxyalkylthio, aryl, substituted aryl, alkenyl (C 2-C 6), alkylthio (C 1-C 6), alkylsulfoxide (C 1-C 6), and alkylsulfonyl (C 1-C 6);
R 1 is selected from the group consisting of H, alkyl (C 1-C 4), and cycloalkyl (C 3-C 6);
R 2 is from the group consisting of H, alkyl (C 1-C 4), haloalkyl (C 1-C 4), alkoxy (C 1-C 4), alkenyl (C 2-C 4), alkynyl (C 2-C 4), aryl and haloaryl, and wherein R 1 and R 2 are alkyl which, together with N, form a ring of at least 3, but not more than 6 members;
R 3 is H or alkyl (C 1-6); and X is selected from the group consisting of oxygen and sulfur.

Original claim 1 of S.N. 782,756 is a verbatim recitation of the above structural formula.[FN4]

FN4. The basic structure of the compounds here involved may be viewed as a combination of two distinct moieties:

Image 3 (1.25▒ X 2.5▒) Available for Offline Print

The portion on the left is a thiadiazole moiety which is a five-membered heterocycle, the members of which have been numbered in accordance with convention. When X is oxygen, the portion on the right is a urea moiety, urea having the formula NH 2-CO-NH 2. When X is sulfur, the portion on the right is a thiourea moiety.

Proceedings in the PTO

Claim 13 was rejected under 35 U.S.C. s 102 as anticipated by Belgian patent No. 743,615, the effective reference date of which is June 23, 1970.

The examiner took the position that appellant was not entitled to the benefit of a filing date prior to the reference date because nowhere in appellant's earlier filed applications was there a written description of the subject matter of claim 13 in "full, clear, and exact terms," as required by 35 U.S.C. s 112. According to the examiner:

> One skilled in the art reading (the portion of the disclosure of S.N. 782,756 relied on by appellant) would simply not conceive of, without more, the new genus reflected in instant claim 13. (Emphasis in original.)

Accordingly, the examiner concluded that inasmuch as the reference discloses several compounds embraced by the appealed claim and has an effective date more than one year prior to the filing date of the present application, it constitutes a statutory bar under s 102.

*1248 In sustaining the examiner's rejection, the board stated:

> In view of the relatively large number of possible values for R, and in the absence of anything in the disclosure to direct one specifically to the subgenus where R is alkylsulfonyl, we cannot agree with appellant's position. * * * To hold otherwise would be to find within appellant's generic description also a description of each subgenus wherein R 1 was selected from a single member of the group disclosed, while retaining the generic description of the remaining variable symbols, and each subgenus obtained by carrying out a similar operation with R 2 and R 3 and X. We think it clear that the single generic description relied on, in the absence of any additional subgeneric disclosure, is incapable of constituting a written description of so many different genera or subgenera of chemical compounds in the manner required by the statute.

The examiner also rejected claim 13 on the ground of double patenting over the claims of S.N. 113,679. 35 U.S.C. s 101 [FN5] was cited as the statutory basis of rejection.[FN6] However, the board sustained the rejection on a different basis, stating that:

> FN5. Section 101 provides:
> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

> FN6. In the examiner's Answer, appellant was required for the first time to eliminate the conflicting claims from all but one of the copending applications pursuant to 37 CFR 1.78(b), which provides:
> Where two or more applications filed by the same applicant, or owned by the same party, contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application.
> Appellant responded to this requirement in his reply brief by electing to prosecute the claims in the present application and indicating that the conflicting claims in S.N. 113,679 would be canceled "at an appropriate time."

The examiner has incorrectly cited 35 U.S.C. 101 as the basis of his rejection. Although claims 1, 9, 19 and 20 of the co-pending, earlier filed application read on subject matter comprehended by the claim here on appeal, none of the former claims are equivalent in scope to the latter claim. Thus the claims of the parent application are not drawn to the same invention as the claim before us, and 35 U.S.C. 101 is not applicable. However, the judicially created doctrine of double patenting of the obviousness type is clearly appropriate in this situation, as appellant is evidently aware since a terminal disclaimer has been filed in this case. (Citations omitted.) Inasmuch as no terminal disclaimer has been filed in the parent application, however, the potential extension of monopoly upon which this rejection is grounded has not been obviated, and the examiner's rejection must be affirmed.

Claim 13 was further rejected "as being unpatentable over a count of Interference No. 98,209," [FN7] as well as on the grounds that the present specification provides inadequate enabling support for the full scope of the claim (35 U.S.C. s 112, first paragraph) and that the claim fails "to define the invention clearly" (35 U.S.C. s 112, second paragraph). The board reversed the latter rejections.

> FN7. S.N. 113,679 was involved in Interference No. 98,209. Prior to the board's decision, but subsequent to the mailing of the examiner's Answer, the interference was terminated in appellant's favor. Accordingly, the board considered the rejection moot.

OPINION

The 35 U.S.C. s 102 rejection.

Appellant does not dispute that the appealed claim is anticipated by the Belgian patent if the present application is not entitled to the earlier filing date of S.N. 782,756. Consequently, the sole issue with respect to this aspect of the appeal is whether the disclosure of S.N. 782,756 describes the subject matter of claim 13.

[1][2] In resolving this issue, we must view the disclosure of the earlier filed application as would a person skilled in the art *1249 and determine whether it reasonably conveys the information that as of the filing date thereof appellant had possession of the class of 5-alkylsulfonyl-1, 3, 4- thiadiazole ureas defined in claim 13. We are satisfied that it does.

A comparison of the appealed claim with the class of compounds disclosed in S.N. 782,756 reveals that the only difference therebetween lies in the definition of the substituent designated by R. In the appealed claim, R is simply alkylsulfonyl (C 1-C 6), whereas in the earlier application, R corresponds to a Markush group of fourteen variable substituents (the R group), one of which is alkylsulfonyl (C 1-C 6).

The practice of describing a class of chemical compounds in terms of a structural formula wherein the substituents thereof are defined as "a member selected from the group consisting of A, B, C, D * * * " was sanctioned by implication in Ex parte Markush, 1925 C.D. 126, 340 O.G. 839, the first decision to consider the propriety of claims so expressed hence, the name "Markush group." It is generally understood that in thus describing a class of compounds an applicant is, in effect, asserting that the members of the Markush group do not fall within any recognized generic class, but are alternatively usable for the purposes of the invention, and therefore, regardless of which of the alternatives is substituted on the basic structure, the compound as a whole will exhibit the disclosed utility.

An example will serve to illustrate this point. Assume that instead of the foregoing structural formula, S.N. 782,756 expressly disclosed a class of herbicides represented by the formula

Image 4 (1 X 2.5) Available for Offline Print

"wherein R is selected from the group consisting of H, alkyl (C 1-C 6), haloalkyl (C 1-C 6), cycloalkyl (C 3-C 6) * * * alkylsulfonyl (C 1-C 6)" (i. e., R as defined in S.N. 782,756). Given the rationale underlying the use of Markush groups, one skilled in the art would view the above formula as a description of fourteen distinct classes of 5-substituted thiadiazole ureas, each possessing herbicidal activity, just as if the application had listed a first structural formula wherein R was hydrogen, a second wherein R was alkyl (C 1-C 6), a third wherein R was haloalkyl (C 1-C 6), and so on.

Although the preceding example was adduced for illustrative purposes, we believe that, in reality, the exemplified structural formula constitutes the essence of appellant's invention and that one skilled in the art would recognize it as such from the earlier filed application.

S.N. 782,756 points up appellant's contribution to the art with the statement that:

> Particularly effective (herbicides) are (thiadiazole ureas) which contain an organic substituent in the 5-position of the thiadiazole portion.

Thus, the focus is unquestionably on the substituents at the 5-position of the thiadiazole moiety, and not on the substituents of the urea moiety. Accordingly, one skilled in the art would regard the structural formula of S.N. 782,756 as signifying that no matter which member of the R group is present on the thiadiazole moiety, the urea moiety may be substituted or unsubstituted.

We thus agree with appellant that a skilled artisan would recognize from the disclosure of S.N. 782,756 fourteen distinct classes of compounds, each class having a single member of the R group at the 5-position of the thiadiazole moiety and variable substituent groups on the urea moiety. This being the case, it follows that S.N. 782,756 describes the subject matter of claim 13 inasmuch as one of the fourteen classes of compounds is the 5-alkylsulfonyl-1, 3, 4-thiadiazole ureas defined therein.

This record presents yet another instance of the sort of "hypertechnical application" of the written description requirement of *1250 s 112 which was recently criticized in In re Johnson, 558 F.2d 1008, 194 USPQ 187 (Cust. & Pat.App.1977).[FN8] Were the board's decision permitted to stand, future applicants, particularly in cases of this nature, would in all likelihood find themselves in the predicament reflected in the following observation by Judge Learned Hand:

> FN8. In that case a class of thermoplastic polyarylene polyethers was disclosed and claimed in

> a 1963 application which became involved in an interference, the award of priority therein being adverse to Johnson and Farnham. The sole interference count recited a single species within the class of polyethers originally claimed. In 1972 a continuation-in-part application was filed containing claims which differed from the broad claims of the earlier application by reciting a proviso that excluded, inter alia, the subject matter of the lost count. Those claims were rejected under 35 U.S.C. s 102 on the basis of a Netherlands patent, which was a counterpart of the 1963 application. There, as here, the benefit of an earlier filing date was denied because the newly claimed subject matter was allegedly not described in the earlier application. In reversing the rejection, the court there observed that the applicants were merely excising the invention of another, to which they were not entitled, rather than creating an artificial subgenus or claiming new matter.

> If, when (applicants) yield any part of what they originally believed to be their due, they substitute a new "invention," only two courses will be open to them: they must at the outset either prophetically divine what the art contains, or they must lay down a barrage of claims, starting with the widest and proceeding by the successive incorporation of more and more detail, until all combinations have been exhausted which can by any possibility succeed. The first is an impossible task; the second is a custom already more honored in the breach than in the observance, and its extension would only increase that surfeit of verbiage which has for long been the curse of patent practice, and has done much to discredit it. It is impossible to imagine any public purpose which it could serve. (Emphasis added.)

Engineering Development Laboratories v. Radio Corp. of America, 153 F.2d 523, 526-27 (CA2 1946).

Aside from reiterating the reasons advanced by the board for affirming the examiner's rejection, the solicitor asserts that In re Ruschig, 379 F.2d 990, 54 CCPA 1551, 154 USPQ 118 (1967), "may be considered controlling in the present appeal." We disagree.

Ruschig involved a claim drawn to a single compound, N-(p- chlorobenzenesulfonyl)-N'-propylurea (the structure of which is reproduced in the opinion). The PTO rejected that claim, which was added by amendment, contending that it was not described in the application as originally filed. As presently pointed out by the solicitor, one of the arguments there advanced to overcome the rejection was that the subject matter of the appealed claim was described in an original claim setting forth the structural formula of a benzenesulfonylurea having two variable substituents defined as Markush groups. Any seeming similarity between Ruschig and the present case is illusory, however, because the structural formula there relied on could have described, at best, only a subgenus including the specific compound claimed, and not the compound itself. In this respect, Ruschig is readily distinguishable from the present case where the exact subgenus claimed is clearly discernible in the generalized formula of the thiadiazole urea set forth in the earlier filed application.

Moreover, it should be readily apparent from recent decisions of this court involving the question of compliance with the description requirement of s 112 that each case must be decided on its own facts. Thus, the precedential value of cases in this area is extremely limited.

Upon the facts of this case, we conclude that the subject matter of claim 13 is described in S.N. 782,756. The other requirements of 35 U.S.C. s 120 presumably having been met, the present application is entitled to the benefit of a filing date prior to the effective date of the Belgian patent. Accordingly, we reverse the rejection of claim 13 under 35 U.S.C. s 102.

***1251** The double patenting rejection.

Although appellant questions the propriety of rejecting claims in one application on the grounds of obviousness type double patenting over claims of a copending application of the same inventor, we leave the resolution of this issue for another day. We choose instead to assume, arguendo, that claim 13 has been properly rejected and to consider whether appellant's terminal disclaimer under 35 U.S.C. s 253 [FN9] overcomes the rejection.

> FN9. Section 253 provides:
> Whenever, without any deceptive intention, a claim of a patent is invalid the remaining claims shall not thereby be rendered invalid. A patentee, whether of the whole or any sectional interest therein, may, on payment of the fee required by law, make disclaimer of any complete claim, stating therein the extent of his interest in such patent. Such disclaimer shall be in writing, and recorded in the Patent and Trademark Office; and it shall thereafter be considered as part of the original patent to the extent of the interest

> possessed by the disclaimant and by those claiming under him.
>
> In like manner any patentee or applicant may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted or to be granted. (Emphasis added.)

[3] As was stated in In re Thorington, 418 F.2d 528, 534, 57 CCPA 759, 765, 163 USPQ 644, 648 (1969):

> (D)ouble patenting rejections usually take one or both of two forms, namely, the "same invention" type "double patenting" identifiable with the statutory provision 35 U.S.C. s 101, saying that an inventor may obtain a patent, interpreted as meaning only one patent; and the "obviousness" type "double patenting," a judicially-created doctrine grounded in public policy rather than statute and primarily intended to prevent prolongation of monopoly by prohibiting claims in a second patent not patentably distinguishing from claims of a first patent. This court has held that a terminal disclaimer is ineffective where it is attempted to twice claim the same invention; however, an "obviousness" type "double patenting" rejection may be obviated by a terminal disclaimer. (Emphasis in original.)

[4] As previously indicated, notwithstanding the examiner's citation of35 U.S.C. s 101, the board relied on the judicially-created doctrine of obviousness type double patenting in upholding the rejection of claim 13 over certain claims of S.N. 113,679.[FN10] As to the effect of appellant's filing of a terminal disclaimer in the present application, however, the board maintained that since no terminal disclaimer had been filed in S.N. 113,679, "the potential extension of monopoly upon which this rejection is grounded has not been obviated * * *." We consider this line of reasoning unsound, inasmuch as the claim in this application, which is all that we are presently concerned with, is subject to the terminal disclaimer. If the present application should go to issue during the pendency of S.N. 113,679, and the latter contains potentially conflicting claims, the proper procedure would be, at that time, to reject those claims for double patenting over the claim of the present application. Appellant's failure to file a terminal disclaimer in S.N. 113,679 at this time cannot justify the denial of the claim here on appeal. Accordingly, we reverse the double patenting rejection.

> FN10. S.N. 113,679, claims 1, 9, 19, and 20 of which were cited by the board in upholding the double patenting rejection, does not appear in the record. However, since appellant has failed to argue otherwise, we assume that the appealed claim is a mere obvious variant of the cited claims.

REVERSED.

562 F.2d 1245, 195 U.S.P.Q. 434

END OF DOCUMENT

Ex parte Parks

U.S. Patent and Trademark Office Board of Patent Appeals and Interferences

No. 93-2740

Decided September 2, 1993
Released January 4, 1994

United States Patents Quarterly Headnotes

PATENTS
[1] Practice and procedure in Patent and Trademark Office -- Reissue -- Broader claims sought (Section 110.1313)
Patentability/Validity -- Specification -- Written description (Section 115.1103)
Claims in reissue application for method of determining nitrogen content of sample were improperly rejected on ground of inadequate descriptive support under 35 USC 112, first paragraph, since originally-filed disclosure need only convey, to one of skill in art, that applicant had possession of concept of what is claimed in order to satisfy description requirement, since lack of literal basis in disclosure for limitation that decomposition step of claims be "conducted in the absence of a catalyst" thus does not establish prima facie case for lack of descriptive support, and since it cannot be held that originally-filed disclosure would not have conveyed concept of effecting decomposition at elevated temperature in absence of catalyst.

PATENTS
[2] Practice and procedure in Patent and Trademark Office -- Reissue -- Broader claims sought (Section 110.1313)
Claims in reissue application for method of determining nitrogen content of sample are overbroad under 35 USC 251, since application was filed more than two years after grant of original patent, since any claim which does not contain negative limitation expressly excluding presence of catalyst in decomposition step of method is broader than original claims, and since claims in question do not accomplish such exclusion by reciting phrase "consisting essentially of" in characterizing decomposition step.

PATENTS
Particular patents -- Chemical -- Nitrogen detection
4,018,562, Parks and Marietta, chemiluminescent nitrogen detection apparatus and method, claims 81-93 in application for reissue rejected.

***1235** Appeal from final rejection of claims in application for reissue of patent (Jill Johnston, primary examiner).

Application of Robert E. Parks and Robert L. Marietta, serial no. 708,810, filed May 31, 1991, continuation of serial no. 340,540, filed April 18, 1989 and abandoned, for reissue of patent no. 4,018,562, granted April 19, 1977 on application serial no. 625,510, filed Oct. 24, 1975 (chemiluminescent nitrogen detection apparatus and method). From final rejection of all claims in application, applicants appeal. Rejection of claims 1-10, 20-22, 55-80, and 94- 106 reversed; rejection of claims 81-93 affirmed.

Before Calvert, vice chairman, and Steiner and Tarring, examiners-in-chief.

Steiner, examiner-in-chief.

This is an appeal from the final rejection of claims 1 through 10, 20 through 22 and 55 through 106, all the claims in this application for reissue of Patent No. 4,018,562 (the '562 patent).

THE INVENTION

The claimed invention is a method for determining the nitrogen content of a sample comprising manipulative steps which include decomposing the sample in an oxygen/inert gas atmosphere at an elevated temperature to obtain nitric oxide and causing the generated nitric acid to undergo a chemiluminescent reaction with ozone.

Claims 1, 81 and 94 are illustrative and read as follows:

1. The method for determining the total chemically combined nitrogen content of a sample comprising the steps:

a. decomposing said sample in one step in the presence of an oxygen-rich atmosphere of oxygen and an inert gas and at a temperature sufficiently above 700 degrees C. that substantially all of the chemically bound nitrogen is recovered as nitric oxide (NO), such decomposition being conducted in the absence of a catalyst,

b. causing the nitric oxide produced by such decomposition to undergo a chemiluminescent reaction with ozone, and

c. determining the magnitude of the chemiluminescent reaction to indicate the quantity of chemically combined nitrogen in said sample. *81. A method for determining the total chemically combined nitrogen content of a sample, said method comprising the steps of: (a) decomposing said sample in one step, said decomposing step consisting essentially of decomposing said sample in the presence of an oxygen-rich atmosphere of oxygen and an inert gas and at a temperature sufficiently above 700 degrees C that substantially all of the chemically bound nitrogen is recovered as nitric acid (NO);*

(b) causing the nitric oxide produced by such decomposition to undergo a chemiluminescent reaction with ozone; and

(c) determining the magnitude of the chemiluminescent reaction to indicate the quantity of chemically combined nitrogen in said sample.

94. A method for determining the total chemically combined nitrogen content of a sample, said method comprising the steps of:

(a) decomposing said sample in one step in the presence of an oxygen-rich atmosphere of oxygen and an inert gas and at a temperature sufficiently above 700 degrees C that substantially all of the chemically bound nitrogen is recovered as nitric oxide (NO) according to the formula:

Image 1 (0.25 X 1.5) Available for Offline Print

(b) causing the nitric oxide produced by such decomposition to undergo a chemiluminescent reaction with ozone; and

(c) determining the magnitude of the chemiluminescent reaction to indicate the quantity of chemically combined nitrogen in said sample.

THE REJECTIONS

Claims 1 through 10, 20 through 22 and 55 through 80 stand rejected under the first paragraph of 35 U.S.C. 112 for lack of adequate descriptive support. Claims 81 through 106 stand rejected under 35 U.S.C. 251 in that they are broader than the originally patented claims. [FN1] In addition, all the ***1236** appealed claims stand rejected under 35 U.S.C. 251 for lack of the requisite "error."

The rejection under the first paragraph of 35 U.S.C. 112, the rejection of claims 94 through 106 under 35 U.S.C. 251 as broader than the original claims, and the rejection of all the appealed claims under 35 U.S.C. 251 for lack of the requisite "error" are reversed; the rejection of claims 81 through 93 under 35 U.S.C. 251 as broader than the original claims is affirmed.

OPINION

The Rejection of Claims 1 through 10, 20 through 22 and 55 through 80 under the first paragraph of 35 U.S.C. 112. The initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention on any ground is always upon the examiner. *In re Oetiker,* 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In rejecting a claim under the first paragraph of 35 U.S.C. 112 for lack of adequate descriptive support, it is incumbent upon the examiner to establish that the originally-filed disclosure would not have reasonably conveyed to one having ordinary skill in the art that an appellant had possession of the now claimed subject matter. *Wang Laboratories, Inc. v. Toshiba Corp.,* 993 F.2d 858, 26 USPQ2d 1767 (Fed. Cir. 1993). Adequate description under the first paragraph of 35 U.S.C. 112 does not require *literal* support for the claimed invention. *In re Herschler,* 591 F.2d 693, 200 USPQ 711 (CCPA 1979); *In re Edwards,* 568 F.2d 1349, 196 USPQ 465 (CCPA 1978; *In re Werthein,* 541 F.2d 257, 191 USPQ 90 (CCPA 1976). Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed. *In re Anderson,* 471 F.2d 1237, 176 USPQ 331 (CCPA 1973).

[1] The examiner contends that the rejected claims lack adequate descriptive support because there is "no literal basis for the" [FN2] claim limitation "in the absence of a catalyst." Clearly, the observation of a lack of literal support does not, in and of itself, establish a *prima facie* case for lack of adequate descriptive support under the first paragraph of 35 U.S.C. 112. *In re Herschler, supra; In re Edwards, supra; In re Wert heim, supra.*

The examiner notes that in *Parks v. Fine,* 773 F.2d 1577, 227 USPQ 432 (Fed. Cir. 1985), involving the claimed subject matter, the limitation "in the absence of a catalyst" was considered material. Suffice it to say, no issue under the first paragraph of 35 U.S.C. 112 for lack of adequate descriptive support for the limitation "in the absence of a catalyst" was before the court.

We are not unmindful of the decision in *Ex parte Grasselli,* 231 USPQ 393 (Bd.App. 1983) *aff'd mem.,* 738 F.2d 453 (Fed. Cir. 1984), which involved claims to a process for the ammoxidation of propane or isobutane employing a catalyst "free of uranium and the combination of vanadium and phosphorus." Under the particular facts in that case, it was held that the negative limitation introduced new concepts in violation of the description requirement of the first paragraph of 35 U.S.C. 112 , citing *In re Anderson, supra.* In the situation before us, [FN3] it cannot be said that the originally-filed disclosure would not have conveyed to one having ordinary skill in the art that appellants had possession of the *concept* of conducting the decomposition step generating nitric acid in the absence of a catalyst. See, for example, column 5 of the '562 patent, first paragraph, wherein FIG. 4 is discussed. Pyrolysis temperatures of between 600 degrees C and 700 degrees C, and above 700 degrees C were employed to achieve conversion of chemically bound nitrogen to nitric oxide. Smooth conversion was obtained above 700 degrees C, while the optimum conversion was found to occur above 900 degrees C. Throughout the discussion which would seem to cry out for a catalyst if one were used, no mention is made of a catalyst. [FN4]

Moreover, according to two declarations by Wentworth, a professor of chemistry at the University of Houston, whose expertise in this particular art has not been challenged, one having ordinary skill in the art would have recognized that the reaction generating nitric oxide, according to the equation disclosed in the '562 patent, is conducted without a catalyst. See *Vas- Cath, Inc. v. Mahurkar,* 935 F.2d 1555, 19 USPQ2d *1237 1111 (Fed. Cir. 1991); *In re Lemin,* 364 F.2d 864, 150 USPQ 546 (CCPA 1966). Thus, it cannot be said that the originally-filed disclosure would not have conveyed to one having ordinary skill in the art the concept of effecting decomposition at an elevated temperature in the absence of a catalyst. *In re Anderson, supra.*

Accordingly, the examiner's rejection of claims 1 through 10, 20 through 22 and 55 through 80 under the first paragraph of 35 U.S.C. 112 for lack of adequate descriptive support is reversed.

The Rejection of Claims 81 through 106 under 35 U.S.C. 251 as Broader than the Original Claims.

We initially observe that on page 6 of the Brief,

appellants agree that any claim in the reissue application that does not contain a limitation that *means* "in the absence of a catalyst" is broader than original claims 1-10 and hence unpatentable under 35 USC 251 (appellants' emphasis).

Claims 81 through 106 do not contain a negative limitation which expressly precludes the presence of a catalyst. However, appellants contend that claims 81 through 93 exclude the presence of a catalyst by virtue of the phrase "consisting essentially of" in characterizing the decomposition step, and that claims 94 through 106 exclude the presence of a catalyst by virtue of the recited equation for the decomposition reaction, which equation does not reflect the presence of a catalyst.

[2] In our opinion, the phrase "consisting essentially of," as employed in claims 81 through 93, limits decomposition to a single step and, in that sense, is redundant since decomposition is performed "in one step." However, it is not apparent and appellants have not explained why the expression "consisting essentially of" excludes the presence of a catalyst during the recited decomposition step. [FN5] It would, therefore, appear that claims 81 through 93 are broader than original claims 1 through 10 and, hence, were properly rejected by the examiner under 35

U.S.C. 251. Accordingly, the examiner's rejection of claims 81 through 93 under 35 U.S.C. 251 is affirmed.

Claims 94 through 106 recite the decomposition reaction in a manner which, according to the Wentworth declarations, means that no catalyst was employed. *In re Lemin, supra*. Accordingly, claims 94 through 106 would not appear broader than original claims 1 through 10 and, hence, the examiner's rejection of claims 94 through 106 under 35 U.S.C. 251 is reversed.

The Rejection of the Appealed Claims Under 35 U.S.C. 251 for Lack of the Requisite Error.

This rejection is reversed essentially for the reasons advocated by appellants on appeal. We emphasize that the practice of submitting claims as a hedge against the possible invalidity of original claims has been judicially sanctioned. See, for example, *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 882 F.2d 1556, 11 USPQ2d 1750 (Fed. Cir. 1989); *In re Altenpohl*, 500 F.2d 1151, 183 USPQ 38 (CCPA 1974); *In re Handel*, 312 F.2d 943, 136 USPQ 460 (CCPA 1963).

In summary, the examiner's rejection of claims 81 through 93 is affirmed; the rejection of claims 1 through 10, 20 through 22, 55 through 80 and 94 through 106 is reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR 1.136(a). See the final rule notice, 54 F.R. 29548 (July 13, 1989), 1105 O.G. 5 (August 1, 1989).

AFFIRMED-IN-PART.

FN1 The ultimate paragraph of 35 U.S.C. 251 reads as follows:

No reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent.

FN2 See page 4 of the Answer, second full paragraph, line 4, and page 7 thereof, last two lines.

FN3 Whether the requirement for an adequate written description has been met is a question of fact and, hence, driven by the exigencies of each case. *Wang Laboratories, Inc. v. Toshiba Corp.*, 993 F.2d 858, 26 USPQ2d 1767 (Fed. Cir. 1993).

FN4 A "catalyst" normally functions to accelerate a particular reaction. See for example, Hawley, *Condensed Chemical Dictionary*, Tenth Edition, 1981, pp. 205 and 206, copies of which are enclosed for appellants' convenience and made of record.

FN5 Compare *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805, 812 , note 6 (Fed. Cir. 1986).

P.T.O. Bd.Pat.App. & Int.

30 U.S.P.Q.2d 1234

END OF DOCUMENT

289 F.3d 1367
62 U.S.P.Q.2d 1917
(Cite as: 289 F.3d 1367)
<KeyCite History>
United States Court of Appeals,
Federal Circuit.

CROWN OPERATIONS INTERNATIONAL, LTD. and Marshall H. Krone, Plaintiffs-Appellants,
v.
SOLUTIA INC., Defendant-Appellee.

No. 01-1144.

DECIDED: May 13, 2002.
Rehearing Denied: June 10, 2002.

Competitor of holder of patents for layered films used to create safety and solar control glass brought suit seeking declaratory judgment that patents were invalid. The United States District Court for the Western District of Wisconsin, John C. Shabaz, J., granted summary judgment denying relief. Competitor appealed. The Court of Appeals, Gajarsa, Circuit Judge, held that: (1) two percent limitation for visible reflectance contribution that was claimed in first patent was not inherent in, and thus was not anticipated by, existing patent; and (2) first patent was not invalid for obviousness; but (3) fact issue as to whether second patent satisfied enablement requirement precluded summary judgment.

Affirmed in part, reversed in part, and remanded.

West Headnotes

[1] Federal Courts k776
170Bk776

Court of Appeals reviews a district court's grant of summary judgment without deference. Fed.Rules Civ.Proc.Rule 56(c), 28 U.S.C.A.

[2] Federal Civil Procedure k2543
170Ak2543

On a motion for summary judgment, the evidence must be viewed in the light most favorable to the party opposing the motion, with doubts resolved in favor of the nonmovant. Fed.Rules Civ.Proc.Rule 56(c), 28 U.S.C.A.

[3] Federal Civil Procedure k2546
170Ak2546

Once party moving for summary judgment has satisfied its initial burden, the opposing party must establish a genuine issue of material fact and cannot rest on mere allegations, but must present actual evidence. Fed.Rules Civ.Proc.Rule 56(c), 28 U.S.C.A.

[4] Federal Civil Procedure k2470.1
170Ak2470.1

Issues of fact are genuine, and thus sufficient to preclude grant of summary judgment, only if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. Fed.Rules Civ.Proc.Rule 56(c), 28 U.S.C.A.

[5] Federal Civil Procedure k2470.1
170Ak2470.1

A disputed fact is material, so that summary judgment may not be granted, if it might affect the outcome of the suit such that a finding of that fact is necessary and relevant to the proceeding. Fed.Rules Civ.Proc.Rule 56(c), 28 U.S.C.A.

[6] Patents k72(1)
291k72(1)

A patent is invalid for anticipation when the same device or method, having all of the elements contained in the claim limitations, is described in a single prior art reference.

[7] Patents k72(1)
291k72(1)

To render a patent invalid for anticipation, an anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed in the prior art and that such existence would be recognized by

persons of ordinary skill in the field of the invention.

[8] Patents k16(2)
291k16(2)

[8] Patents k16(3)
291k16(3)

[8] Patents k16.13
291k16.13

[8] Patents k36.1(1)
291k36.1(1)

Obviousness of device or method claimed in a patent is a legal conclusion based on underlying facts of four general types, all of which must be considered by the trier of fact: (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) any objective indicia of nonobviousness.

[9] Patents k16(4)
291k16(4)

[9] Patents k26(1)
291k26(1)

A determination of obviousness of method of device for which patent protection is sought cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention; rather, there must be a teaching or suggestion within the prior art, within the nature of the problem to be solved, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources, to select particular elements, and to combine them as combined by the inventor.

[10] Patents k99
291k99

Inquiry into whether patent is invalid based on lack of a written description is a factual one and must be assessed on a case-by-case basis. 35 U.S.C.A. § 112.

[11] Patents k99
291k99

In order to satisfy the written description requirement, the patent disclosure as originally filed does not have to provide in haec verba support for the claimed subject matter at issue; nonetheless, the disclosure must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention. 35 U.S.C.A. § 112.

[12] Patents k99
291k99

Satisfaction of possession test, standing alone, is not always sufficient to meet the written description requirement for patent protection. 35 U.S.C.A. § 112.

[13] Patents k99
291k99

Written description requirement for a patent is satisfied by the patentee's disclosure of such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention; put another way, one skilled in the art, reading the original disclosure, must reasonably discern the limitation at issue in the claims. 35 U.S.C.A. § 112.

[14] Patents k314(5)
291k314(5)

Whether a patent claim is enabled is a question of law, although based upon underlying factual findings. 35 U.S.C.A. § 112.

[15] Patents k66(1.25)
291k66(1.25)

Two percent limitation for visible reflectance contribution that was claimed in patent for solar control film used in safety and solar control glass was not inherent in, and thus was not anticipated by, existing patent, which disclosed other limitations claimed in patent, but did not claim two percent limitation.

[16] Patents k65
291k65

Inherency of a disclosure in prior art, as will permit a subsequent patent to be rendered invalid due to anticipation, may not be established by probabilities or possibilities, and the mere fact that a certain thing may result from a given set of circumstances is not sufficient.

[17] Federal Civil Procedure k2544
170Ak2544

Party moving for summary judgment has the burden to show that there is an absence of evidence to support the non-moving party's case, and the non-moving party must affirmatively demonstrate by specific factual allegations that a genuine issue of material fact exists for trial. Fed.Rules Civ.Proc.Rule 56(c), 28 U.S.C.A.

[18] Patents k112.5
291k112.5

A patent enjoys a presumption of validity, which can be overcome only through clear and convincing evidence. 35 U.S.C.A. § 282.

[19] Patents k16.14
291k16.14

Patent for solar control film used in safety and solar control glass, which described a film which contributed no more than about two percent visible reflectance, was not invalid for obviousness; no showing was made that prior art contained a teaching, suggestion, or motivation to reduce the reflectance contribution of the solar control film in question.

[20] Patents k99
291k99

Written description and enablement requirements for patents, while related and springing from the same factual predicates, each carry a separate purpose. 35 U.S.C.A. § 112.

[21] Patents k99
291k99

Purpose of the enablement requirement for patents is to ensure that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims. 35 U.S.C.A. § 112.

[22] Patents k99
291k99

A patent specification may contain a disclosure that is sufficient to enable one skilled in the art to make and use the invention, and yet fail to comply with the description of the invention requirement. 35 U.S.C.A. § 112.

[23] Federal Civil Procedure k2508
170Ak2508

Genuine issue of material fact as to whether a person of ordinary skill in the pertinent art could make or use invention claimed in patent for method of eliminating optical distortion in safety and solar control glass, as would allow patent to satisfy enablement requirement, precluded summary judgment in competitor's suit seeking declaratory judgment regarding validity of patent. 35 U.S.C.A. § 112; Fed.Rules Civ.Proc.Rule 56(c), 28 U.S.C.A.

Patents k328(2)
291k328(2)

4,017,661, 5,091,258. Cited.

Patents k328(2)
291k328(2)

4,973,511. Valid.

***1370** Joseph T. Leone, DeWitt Ross and Stevens, S.C., of Madison, WI, argued for plaintiffs-appellants. With him on the brief was Joseph A. Ranney.

Gregory E. Upchurch, Thompson Coburn LLP, of St. Louis, MO, argued for defendant-appellee. With him on the brief were Kenneth R. Heineman, and Dudley W. Von Holt.

Before LOURIE, CLEVENGER, and GAJARSA, Circuit Judges.

GAJARSA, Circuit Judge.

Crown Operations International, Ltd., and Mr. Marshall H. Krone (collectively "Crown"), appeal the decision of the United States District Court for the Western District of Wisconsin denying Crown declaratory relief that Solutia's U.S. Patent No. 4,973,511 ("the '511 patent") is invalid for lack of novelty and non-obviousness, and that Solutia's U.S. Patent No. 5,091,258 ("the '258 patent") is invalid for lack of enablement and written description. *Crown Operations Int'l, Ltd. v. Solutia, Inc.*, No. 99-C-802-S, slip op. at 8 (W.D.Wis. Aug. 30, 2000) (memorandum decision and order granting summary judgment) ("*August 30 Order* "); *Crown Operations Int'l, Ltd. v. Solutia,*

Inc., No. 99-C-802-S, slip op. at 24, 27 (W.D.Wis. Aug. 22, 2000) (same) ("*August 22 Order* "). Because we find no error in the district court's opinion with respect to the '511 patent, we affirm that portion of the district court's decision. However, because the district court erred in its analysis of enablement for the '258 patent, and did not address the written description issue for the '258 patent, we vacate the district court's grant of summary judgment on that issue and remand for additional proceedings consistent with this opinion.

I. BACKGROUND

The patents at issue in this appeal relate to layered films used to create safety and solar control glass. An example is an automobile windshield. Most windshields have two layers of glass with a multi-layer film between the glass layers. The multi-layer film adds properties to the glass assembly, such as impact resistance or providing a conductive layer that facilitates defrosting the windshield. An inner layer of the film has solar control properties to selectively reflect, absorb (and thus convert to heat) or transmit defined percentages of certain wavelengths of light. This inner layer is called the solar control film. It is made of a substrate coated by one or more layers of metal or metallic substances. '511 patent, col. 3, l. 64 to col. 4, l. 2. Typically, manufacturers laminate the solar control film between layers of plasticized polyvinyl butyral ("PVB") (sometimes called the "safety film") in a process known as encapsulation. Then, the encapsulated solar control film is sandwiched between two pieces of glass for a final assembly of multi-layer glass with safety and solar control properties.

A. The '511 Patent

The '511 patent is directed to the problem that the metal-coated substrate, *i.e.*, solar control film, tends to wrinkle during encapsulation causing visual distortions. The '511 patent claims to mask the wrinkles from detection by the human eye by ***1371** limiting to two percent or less the visible light reflection contribution of the solar control film compared to reflection from a complete assembly of glass, PVB and solar control film. '511 patent, col. 4, ll. 46-49, col. 8, l. 66 to col. 9, l. 6, col. 14, l. 67 to col. 15, l. 2. Figure 1 from the '511 patent, set forth below, shows the layers in a complete assembly.

Image 1 (2.5▒ X 4▒) Available for Offline Print

FIG. 1

The complete safety and solar control glass assembly 10 includes two outer glass layers 28 & 30, PVB layers 22 & 23, and the solar control film 20. The solar control film is comprised of a substrate layer 16 and solar control coating 18. '511 patent, col. 3, ll. 41-53, col. 7, ll. 2-4, col. 10, l. 15. Figure 3 from the '511 patent, set forth below, shows the sub-layers of the solar control coating 18.

Image 2 (2▒ X 3.75▒) Available for Offline Print

FIG. 3

Layer 18 is made of multiple sub-layers. Layers 34 and 36 are metal oxide, and layer 38 is metal. '511 patent, col. 5, ll. 12-14. In addition, the ' 511 patent notes that "[p]rior automotive windshields have visible light reflection contributions for their solar films of three percent or greater." Further, it relates that the primary method of achieving a low solar control film reflectance contribution is by providing a specially-designed solar coating. '511 patent, col. 4, ll. 56-65.

On December 16, 1999, Crown sued Solutia (the "Initial Complaint"), seeking, among various other relief, a declaration that the '511 patent was invalid for anticipation and obviousness. Upon the parties' cross-motions for summary judgment, the district court found the '511 patent not anticipated and not invalid for obviousness. *August 22 Order* at 24, 27. We discuss herein only those portions of the *August 22 Order* relevant to the issues on appeal, which relate solely to the summary judgment finding that the '511 patent was not ***1372** invalid on the grounds of anticipation and obviousness.

Claim 1, the only independent claim of the '511 patent, is set forth below, with the element numbers from Figure 1 inserted into the claim.

1. A composite solar/safety film [24] for use in a laminated window assembly [10] comprising:
a flexible, transparent plastic substrate layer [16] having a carrier surface and an opposing back surface;
a multilayer solar control coating [18] on said carrier surface, said coated substrate defining a solar control film [20]; and
at least one flexible, transparent, energy absorbing

plastic safety layer [23 and/or 22] bonded to a surface of said solar control film;

wherein said *solar control film contributes no more than about 2% visible reflectance,* based on total visible incident radiation, in a laminated window assembly containing said composite solar/safety film laminated to at least one rigid transparent member [30 and/or 28].

'511 patent, col. 14, l. 57 to col. 15, l. 4 (emphasis added and emphasized numbers added to identify elements shown in Figure 1 above).

Crown argued that U.S. Patent No. 4,017,661 to Gillery (the "Gillery patent") anticipates the '511 patent. The district court held otherwise, because, while the Gillery patent discloses the first three limitations of claim 1 of the '511 patent, it does not disclose the two percent visible reflectance limitation. The court found that neither the Gillery patent claims nor its description expressly disclose a two percent limit on reflectance contribution from the solar control film layer. Crown argued that the two percent limitation was inherently present in the Gillery patent's teachings because the Gillery patent disclosed an assembly with PVB layers, substrate layer, and substrate metal-coating--arguably of the same composition and thickness of the films disclosed by the '511 patent. Thus, Crown argued, because the structure, thickness and materials of the assembly were the same or within the same range(s), the Gillery patent must inherently disclose a two percent limitation. The district court rejected this argument because it found that none of the embodiments disclosed by the Gillery patent meet the two percent visible light reflectance limit. [FN1]

> FN1. The district court, applying a similar analysis, also found that UK Patent Application GB 2 057 355 (the "UK patent") did not anticipate the '511 patent because it did not have the two percent limitation.

In its *August 22 Order,* the district court also held that the '511 patent was not rendered invalid for obviousness by Gillery or the other prior art cited by Crown because no prior art discloses: (i) that reflectance below two percent will mask wrinkles; (ii) a solar control film layer with reflectance below two percent; or (iii) any suggestion, motivation or teaching to reduce solar control film visible light reflectivity below two percent. Although the prior art generally sought to reduce visible light reflectivity, it also taught disadvantages of a very thin metal-coating on the substrate, including sacrificing infrared reflectivity. Thus, it taught that the proper compromise to achieve the conflicting goals of infrared (non-visible light) reflectance, visible light transmission and conductivity ***1373** was a solar control film with a visible light reflectivity greater than two percent.

B. The '258 Patent

The '258 patent is directed at eliminating optical distortion, called "applesauce," in safety and solar control glass assemblies of the type discussed above for the '511 patent. The '258 patent discloses a method to control distortion otherwise caused by the safety and solar film layer by measuring and controlling the texture of the surface of the PVB layers. The method expresses texture using a "wave index" and a "roughness value." The wave index calculation is at issue in this appeal. Wave index indicates the relative waviness of the surface of the PVB. Determining wave index involves measuring the surface of the PVB and then aggregating the measurements into a single number, the wave index, through a calculation purportedly described in the '258 patent.

The '258 patent directs one to use an instrument to physically measure the waviness of the surface of the PVB and capture the measurement into an electronic "trace line" representing the contours of the PVB surface. '258 patent, col. 7, II. 54-65. Since the "trace line" is stored electronically, a computer program is used to calculate wave index from the trace. Three figures from the '258 patent, given below, provide examples of PVB surface trace lines.

Image 3 (3▒ X 4▒) Available for Offline Print

The rules for calculating the wave index implement a "smoothing" function. The smoothing process seeks to eliminate minor inflection points (peaks or valleys) to simplify the calculation of wave index. '258 patent, col. 7, I. 66 to col. 8, I. 2.

In the Initial Complaint, Crown sought a declaration that the '258 patent was invalid for anticipation and obviousness. Then, on May 26, 2000, Crown amended the complaint (the "Amended Complaint") to additionally claim in Count VI that the '258 patent is invalid under 35 U.S.C. § 112, first paragraph, because it lacked enablement and written description due to ambiguities in the

disclosed wave index calculation. In its *August 22 Order,* the district court found the '258 patent not anticipated and not invalid for obviousness. *August 22 Order* at 28-29.

With respect to Count VI of Crown's amended complaint, Solutia moved for ***1374** summary judgment on Crown's enablement and written description claim. Crown opposed Solutia's summary judgment motion, arguing that the '258 patent did not meet the enablement and written description requirements. The district court found the '258 patent not invalid for lack of enablement, but did not discuss in its opinion the written description requirement. *August 30 Order* at 8-13. We discuss herein only those portions of the *August 30 Order* relevant to the issues on appeal, which relate to summary judgment finding the '258 patent not invalid on the grounds of enablement and the procedural disposition of the written description issue.

Claim 1 of the '258 patent is set forth below. In the language of this claim, "laminate" refers to the complete glass, PVB and solar control film assembly, and "functional performance layer" refers to the solar control coating. '258 patent, col. 3, II. 45-65.

> 1. A laminate which is substantially free of reflected distortion when used in a safety glazing comprising:
> a transparent, thermoplastic substrate layer, optionally surface treated or coated, bearing one or more functional performance layers; and
> at least one layer of plasticized polyvinyl butyral bonded on one side to a functional performance layer or the substrate layer and having a roughened deairing surface on its other side characterized by a roughness value, Rz, of at least 10 micrometers;
> said at least one plasticized polyvinyl butyral [PVB] layer, before bonding to the substrate layer or functional performance layer, *possessing low surface waviness on each side characterized by a wave index value, WI, of less than 15,000 square micrometers.*
> '258 patent, col. 12, II. 2-16 (emphasis added).

Crown argued that the rules disclosed by the '258 patent for calculating wave index are not sufficiently precise to enable a person of ordinary skill in the art to practice the '258 patent without undue experimentation. The wave index calculation as described by the '258 patent is set forth below.

> In this regard, considering the waviness profile as a series of peaks and valleys, the smoothing rules of the program consider an inflection point to be a true peak or valley if it is: i) at least 100 micrometers away from the immediately preceding prior peak or valley and ii) at least 0.5 micrometer above or below the immediately preceding prior peak or valley, a valley being at least 0.5 micrometer below the immediately preceding prior peak. Pitch (P) is the distance between one valley and the next valley or in other words across the base of a peak. Average amplitude (H avg) and average pitch (P avg) are determined by the program for the smoothed trace of ten 12.5 mm tracing lengths (the second five lengths being 90 o to the first five lengths). From the average of the averaged H's and P's, a WI value is computed from the equation: Wave Index (WI) = (H avg) x (P avg) where H avg and P avg are in microns.
> '258 patent, col. 8, II. 3-19.

Crown asserted that according to the disclosed wave index "calculation," one of ordinary skill in the pertinent art would not know whether to instruct the smoothing program to disregard a peak by comparing it to an immediately preceding peak, or to a valley. The district court held that common sense and the clarifying clause "a valley being at least 0.5 micrometer ***1375** below the immediately preceding prior peak" defeated Crown's argument. Thus, the district court held that the alleged grammatical ambiguities in the rules disclosed for calculating wave index did not invalidate the patent for lack of enablement.

Crown timely appealed the district court's two orders, raising the issues of anticipation and obviousness of the '511 patent, and lack of enablement and written description of the '258 patent. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

II. STANDARD OF REVIEW

[1][2][3][4][5] We review a district court's grant of summary judgment without deference. *Atmel Corp. v. Info. Storage Devices, Inc.,* 198 F.3d 1374, 1378, 53 USPQ2d 1225, 1227 (Fed.Cir.1999). Summary judgment is appropriate when the moving party demonstrates that "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c); *Celotex Corp. v. Catrett,* 477 U.S. 317, 322-23, 106 S.Ct. 2548, 91 L.Ed.2d 265

(1986). On summary judgment, the evidence must be viewed in the light most favorable to the party opposing the motion, *Poller v. Columbia Broad. Sys., Inc.,* 368 U.S. 464, 473, 82 S.Ct. 486, 7 L.Ed.2d 458 (1962), with doubts resolved in favor of the nonmovant, *Cantor v. Detroit Edison Co.,* 428 U.S. 579, 582, 96 S.Ct. 3110, 49 L.Ed.2d 1141 (1976); *Transmatic, Inc. v. Gulton Indus., Inc.,* 53 F.3d 1270, 1274, 35 USPQ2d 1035, 1038 (Fed.Cir.1995). Once the moving party has satisfied its initial burden, the opposing party must establish a genuine issue of material fact and cannot rest on mere allegations, but must present actual evidence. *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). Issues of fact are genuine only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* A disputed fact is material if it might affect the outcome of the suit such that a finding of that fact is necessary and relevant to the proceeding. *Id.; General Mills, Inc. v. Hunt-Wesson, Inc.,* 103 F.3d 978, 980, 41 USPQ2d 1440, 1442 (Fed.Cir.1997).

[6][7] A patent is invalid for anticipation when the same device or method, having all of the elements contained in the claim limitations, is described in a single prior art reference. *Richardson v. Suzuki Motor Co.,* 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed.Cir.1989); *Perkin-Elmer Corp. v. Computervision Corp.,* 732 F.2d 888, 894, 221 USPQ 669, 673 (Fed.Cir.1984). An anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed in the prior art and that such existence would be recognized by persons of ordinary skill in the field of the invention. *See In re Spada,* 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed.Cir.1990); *Diversitech Corp. v. Century Steps, Inc.,* 850 F.2d 675, 678, 7 USPQ2d 1315, 1317 (Fed.Cir.1988).

[8] Obviousness is a legal conclusion based on underlying facts of four general types, all of which must be considered by the trier of fact: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) any objective indicia of nonobviousness. *See Graham v. John Deere Co.,* 383 U.S. 1, 17-18, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966); *Continental Can Co. USA, Inc. v. ***1376** Monsanto Co.,* 948 F.2d 1264, 1270, 20 USPQ2d 1746, 1750-51 (Fed.Cir.1991); *Panduit Corp. v. Dennison Mfg. Co.,* 810 F.2d 1561, 1566-68, 1 USPQ2d 1593, 1594 (Fed.Cir.1987).

[9] "Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention." *ATD Corp. v. Lydall, Inc.,* 159 F.3d 534, 546, 48 USPQ2d 1321, 1329 (Fed.Cir.1998). There must be a teaching or suggestion within the prior art, within the nature of the problem to be solved, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources, to select particular elements, and to combine them as combined by the inventor. *See Ruiz v. A.B. Chance Co.,* 234 F.3d 654, 665, 57 USPQ2d 1161, 1167 (Fed.Cir.2000); *ATD Corp.,* 159 F.3d at 546, 48 USPQ2d at 1329; *Heidelberger Druckmaschinen AG v. Hantscho Commercial Prods., Inc.,* 21 F.3d 1068, 1072, 30 USPQ2d 1377, 1379 (Fed.Cir.1994) ("When the patented invention is made by combining known components to achieve a new system, the prior art must provide a suggestion or motivation to make such a combination.").

[10][11][12][13] The written description inquiry is a factual one and must be assessed on a case-by-case basis. *See Vas-Cath Inc. v. Mahurkar,* 935 F.2d 1555, 1561, 19 USPQ2d 1111, 1116 (Fed.Cir.1991) (quoting *In re Smith,* 59 C.C.P.A. 1025, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) ("Precisely how close the original description must come to comply with the description requirement of § 112 must be determined on a case-by-case basis.")). In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide in haec verba support for the claimed subject matter at issue. *See Fujikawa v. Wattanasin,* 93 F.3d 1559, 1570, 39 USPQ2d 1895, 1904 (Fed.Cir.1996). Nonetheless, the disclosure must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention, *Vas-Cath Inc.,* 935 F.2d at 1563-64, 19 USPQ2d at 1116-17, although we have also clarified that the possession test alone is not always sufficient to meet the written description requirement, *Enzo Biochem, Inc. v. Gen-Probe Inc.,* 285 F.3d 1013, 1020-21 (Fed.Cir.2002). As such, "the written description requirement is satisfied by the patentee's disclosure of 'such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.' " *Enzo Biochem,* 285 F.3d at 1021 (quoting *Lockwood v.*

American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed.Cir.1997)). Put another way, one skilled in the art, reading the original disclosure, must reasonably discern the limitation at issue in the claims. *Waldemar Link, GmbH & Co. v. Osteonics Corp.*, 32 F.3d 556, 558, 31 USPQ2d 1855, 1857 (Fed.Cir.1994).

[14] Whether a claim is enabled under 35 U.S.C. § 112, first paragraph is a question of law, although based upon underlying factual findings. See *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed.Cir.1996); *In re Goodman*, 11 F.3d 1046, 1049-50, 29 USPQ2d 2010, 2013 (Fed.Cir.1993).

III. DISCUSSION

A. The '511 Patent

On appeal, Crown describes various purported errors in the district court's analysis ***1377** of the validity of the '511 patent. Despite Crown's contentions, we ascertain no error requiring reversal of the district court's determination of validity over Crown's claims of anticipation and obviousness.

[15][16] Regarding alleged anticipation by the Gillery patent, on its face the Gillery patent does not disclose or discuss a two percent limitation for the reflectance contribution of the solar control film. Crown maintains that the '511 patent merely claims a preexisting property inherent in the structure disclosed in the prior art. Crown urges us to accept the proposition that if a prior art reference discloses the same structure as claimed by a patent, the resulting property, in this case, two percent solar control film reflectance, should be assumed. We decline to adopt this approach because this proposition is not in accordance with our cases on inherency. If the two percent reflectance limitation is inherently disclosed by the Gillery patent, [FN2] it must be necessarily present and a person of ordinary skill in the art would recognize its presence. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed.Cir.1999); *Continental Can*, 948 F.2d at 1268, 20 USPQ2d at 1749. Inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Id.* at 1269, 20 USPQ2d at 1749 (quoting *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981)).

FN2. In order to claim "equivalent structure" between the Gillery patent and the '511 patent, Crown's inherency argument rests on a precondition of its own making--that the Gillery patent discloses use of TiO_2, even though it specifies TiOx, where x is greater than 1.0 but less than 2.0. Although Crown vigorously argues this point, we do not reach this issue because even if Crown is correct that the structures are equivalent, Crown's inherency argument fails for the reasons set forth herein.

[17][18] In arguing inherent disclosure of the two percent limitation in the Gillery patent, Crown bears an evidentiary burden to establish that the limitation was necessarily present. [FN3] The moving party in a summary judgment motion has the burden to show "that there is an absence of evidence to support the non-moving party's case;" the non-moving party must affirmatively demonstrate by specific factual allegations that a genuine issue of material fact exists for trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). A patent enjoys a presumption of validity, *see* 35 U.S.C. § 282, which can be overcome only through clear and convincing evidence, *see United States Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1563, 41 USPQ2d 1225, 1232 (Fed.Cir.1997). Given the presumption of validity afforded the '511 patent, Crown has failed to meet its burden because it has not presented sufficient evidence to rebut the facial evidence offered by Solutia that the Gillery patent does not ***1378** disclose the two percent limitation. *See Eli Lilly & Co. v. Barr Lab. Inc.*, 251 F.3d 955, 962, 58 USPQ2d 1869, 1874 (Fed.Cir.2001) ("[A] moving party seeking to have a patent held not invalid at summary judgment must show that the nonmoving party, who bears the burden of proof at trial, failed to produce clear and convincing evidence on an essential element of a defense upon which a reasonable jury could invalidate the patent."); *In re Robertson*, 169 F.3d at 745 (recognizing that extrinsic evidence may be required to establish inherency). Instead, Crown offers only an assumption and its own contentions. [FN4]

FN3. Crown's reliance on *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 36 USPQ2d 1225 (Fed.Cir.1995), and *O.I. Corp. v. Tekmar Co.*, 115 F.3d 1576, 42 USPQ2d 1777 (Fed.Cir.1997), to characterize the two percent limitation as a "performance limitation" similar to the claim terms at issue in those cases is unpersuasive and overbroad. Respectively, *Pall* and *Tekmar* dealt with the claim terms "skinless" and "passage." Beyond the readily apparent difference between these potentially broad terms and the precise specification of a two percent limit in the '511 patent, characterizing a claim limitation as a "performance characteristic" is not helpful as to whether the "necessarily present" requirement of inherency is met.

FN4. As indicated by this Court's questions at oral argument concerning the seemingly direct route to prove that the Gillery patent contains the two percent limitation implementing an embodiment of the Gillery patent and testing it this Court finds puzzling Crown's reluctance regarding this approach to generate extrinsic proof that the Gillery patent inherently meets the two percent limitation.

Crown also argues that the district court erred by comparing reflectance values in the Gillery patent to non-corresponding values in the '511 patent. *August 22 Order* at 23-24. While perhaps the district court could have been more careful to explain the basis of its comparison, on a close reading of the district court's analysis we find that the alleged

improper comparison only supported the district court's primary point that no embodiment of the Gillery patent disclosed the two percent limitation, a conclusion that Crown has not shown to be in error.

[19] Finally, Crown argues that various prior art references invalidate the '511 patent as obvious in view of such prior art. Crown's arguments lack merit because it has not shown that the prior art contains a teaching, suggestion or motivation to reduce the reflectance contribution of the solar control film to "no more than about two percent," and the district court properly concluded that there was no such teaching, suggestion or motivation in the prior art cited by Crown. *See Ruiz,* 234 F.3d at 665, 57 USPQ2d at 1167; *In re Rouffet,* 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed.Cir.1998).

B. The '258 Patent

On appeal, Crown argues that the district court erred in analyzing the impact of the ambiguities in the wave index calculation on the enablement requirement for the '258 patent. In addition to its enablement attack, Crown also argues that the '258 patent does not meet the written description requirement of § 112, first paragraph.

[20][21][22] The two requirements, while related and springing from the same factual predicates, [FN5] each carry a separate purpose. The purpose of the enablement requirement is to "ensure[ ] that the public ***1379** knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims." *Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys.,* 166 F.3d 1190, 1196, 49 USPQ2d 1671, 1675 (Fed.Cir.1999). One of our predecessor courts has held the enablement and written description requirements to be separate and distinct, and has held that a "specification may contain a disclosure that is sufficient to enable one skilled in the art to make and use the invention and yet fail to comply with the description of the invention requirement." *In re Barker and Pehl,* 559 F.2d 588, 591, 194 USPQ 470, 472 (CCPA 1977). Subsequently, this court has held that the purpose of the written description is distinct from merely explaining how to make and use the invention. *See Enzo Biochem,* 285 F.3d at 1020-22; *Vas-Cath,* 935 F.2d at 1563-64, 19 USPQ2d at 1117. In light of the odd procedural setting of the written description issue in this appeal, our disposition of this appeal based on enablement, and given that the two requirements are distinct and each are necessary, we do not reach the written description issue except to note that it appears to remain available for adjudication or disposition by the district court on remand. [FN6]

FN5. Also springing from these same underlying factual predicates is the § 112, second paragraph, definiteness requirement. This requirement is distinct from the enablement and description requirements, which arise from § 112, first paragraph.

[D]efiniteness and enablement are analytically distinct requirements, even though both concepts are contained in 35 U.S.C. § 112. The definiteness requirement of 35 U.S.C. § 112, ¶ 2 is a legal requirement, based on the court's role as construer of patent claims ... Definiteness requires the language of the claim to set forth clearly the domain over which the applicant seeks exclusive rights.... The test for whether a claim meets the definiteness requirement is "whether one skilled in the art would understand the bounds of the claim when read in light of the specification."

Process Control Corp., 190 F.3d at 1358 n. 2, 52 USPQ2d at 1034 n. 2 (internal citations omitted). *See also* 3 Donald S. Chisum, Chisum on Patents, § 8.03 at 8-14 (2001) (noting the difference between the requirements of "definiteness, which claims must meet, from the requirements of enablement, which the disclosures of the specification must meet").

FN6. Based on the record before us, the written description issue has the following procedural posture: (i) Crown's Count VI of its amended complaint raised the written description issue; (ii) Solutia's summary judgment motion argued that the '258 patent met the written description requirement; (iii) in opposition Crown argued that the written description requirement was not met; (iv) the district court did not dispose of the written description issue or discuss the issue in its opinion in a way that enables our review; and (v) Crown preserved the written description issue in its appeal to this court and thus has not waived its further adjudication on remand.

[23] Turning to the enablement issue, we agree with Crown that the ambiguities and lack of specified boundary conditions, and Crown's proffered evidence concerning the same, raise a genuine issue of material fact as to whether a person of ordinary skill in the pertinent art could make or use the invention of the '258 patent [FN7] without undue experimentation. *White Consol. Indus. v. Vega Servo-Control,* 713 F.2d 788, 791, 218 USPQ 961, 963-64 (Fed.Cir.1983). The district court found otherwise. However, it appears not to have considered the statements of Crown's expert concerning the effect of unspecified boundary conditions on the calculation of wave index.

FN7. All seventeen claims of the '258 patent refer to wave index, thus they all stand or fall together.

Following the reasoning of the district court, Solutia argues that a person of ordinary skill in the pertinent art could overcome any ambiguities in the wave index calculation without undue experimentation by testing a limited number of possibilities for computing the wave index. In response, Crown offers statements of its expert that the '258 patent does not define amplitude and that a person of ordinary skill in the art would not know whether to measure amplitude: (i) from a centerline running horizontally through the "middle" of the trace; (ii) from "peak-to-peak," *i.e.,* from the bottom of a valley to the top of a peak; or (iii) from some other baseline or reference running horizontally somewhere through the trace. On its face, the '258 patent does not define amplitude. However, average amplitude directly impacts the wave index calculation because wave index ***1380** is the result of multiplying average amplitude by average pitch. Simply put, the wave index calculation would produce two separate numbers if calculated with a centerline versus a "peak-to-peak" amplitude. Worse yet, a range of various wave index values are possible for amplitude baselines running horizontally somewhere through the trace at various locations. To show that the wave index calculation is enabled, Solutia cites various details from the '258 patent concerning how to perform the test to generate a trace of the PVB surface to calculate wave index. However, Solutia does not present sufficient evidence to rebut Crown's demonstration of the amplitude ambiguity in the wave index calculation. This is so because: (i) the amplitude is a direct input to the critical claim limitation, a wave index of less than 15,000 square micrometers; and (ii) the novel aspects of the invention must be disclosed and not left to inference, that is, a patentee may not rely on the inference of a person of ordinary skill in the pertinent art to supply such novel aspects. *See Genentech Inc. v. Novo Nordisk A/S,* 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed.Cir.1997) (stating that the knowledge of a hypothetical person of ordinary skill in the art cannot be used to supply the patentable aspects of the invention).

Compounding the amplitude ambiguity, Crown also notes that the wave index is the result of two independently varying, unbounded terms: average pitch and average amplitude. On its face, this does not seem to be a problem. However, Crown's expert noted that because boundary conditions are not specified, the claim covers inoperative embodiments. For example, a wave index of 15,000 square micrometers results from an average height of 1000 micrometers multiplied by an average pitch of 15 micrometers. Yet, according to Crown's expert, an average height of 1000 micrometers would not be acceptable for the PVB. As with the amplitude ambiguity, the problem goes well beyond this single example because a full range of resulting inoperative embodiments are possible for values of average height and average pitch that, when multiplied, produce a wave index value that meets the limitation of the claim. Such inoperative embodiments do not necessarily invalidate the claim. *See Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576-77, 224 USPQ 409, 414 (Fed.Cir.1984); *In re Cook*, 58 C.C.P.A. 1049, 439 F.2d 730, 735, 169 USPQ 298, 302 (1971) (noting that although claims may read on some inoperative embodiments, this does not necessarily invalidate the claim if the necessary information to limit the claims to operative embodiments is known to a person of ordinary skill in the art). [FN8] However, the inoperative embodiments support Crown's assertion that there is a genuine issue of material fact with respect to enablement. *See Atlas Powder*, 750 F.2d at 1576-77; *see also Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358-59, 52 USPQ2d 1029, 1034-35 (Fed.Cir.1999) (holding that the district court failed in its ***1381** claim construction to consider the effect of inoperative embodiments on invalidity due to lack of enablement). [FN9]

FN8. The court in *In re Cook* further notes that a claim may be invalid if it reads on significant numbers of inoperative embodiments. *In re Cook*, 439 F.2d at 734, 169 USPQ at 301-02 (citing *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 336 U.S. 271, 276-77, 69 S.Ct. 535, 93 L.Ed. 672, 80 USPQ 451, 453 (1949)). *See also In re Moore*, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971) (noting that the question is whether the scope of enablement conveyed by the disclosure to a person of ordinary skill in the art is commensurate with the scope of protection taught by the claims); Chisum, § 7.03[7][a] at 7-108 & n. 6.

FN9. The inoperative embodiment inquiry informs the enablement inquiry; they are not the same inquiry. *Nat'l Recovery Techs.*, 166 F.3d at 1196, 49 USPQ2d at 1676.

Further compounding the ambiguities with the wave index rules, the ' 258 patent's rules for determining which inflection points are "true" inflection points additionally support Crown's argument that it has raised a genuine issue of material fact. Crown demonstrated in various ways through its experts and arguments the potential indeterminacy in the rules. Solutia's expert admitted that there was some ambiguity in the rules with respect to whether a preceding peak or valley was the reference point in selecting a "true" peak or valley.

Solutia argues that even if the disclosed wave index calculation has ambiguities and is indeterminate, a person of ordinary skill in the pertinent art would be able to make and use the invention with some experimentation, but less than "undue" experimentation. Solutia argues that such a skilled person would only have to try two possibilities for amplitude, centerline and "peak- to-peak," and that experimenting to discover which of two possibilities to use is well within the boundary of undue experimentation. Crown counters that the amplitude ambiguity and potential inoperative embodiments, combined with the ambiguities in the smoothing rules, seems to suggest a wide range of possibilities which one must try. [FN10] With this wide range of possibilities, we agree that Crown has raised a genuine issue of material fact as to the amount and type of experimentation required, facts that will determine whether such experimentation is undue. *See Enzo Biochem Inc., v. Calgene Inc.*, 188 F.3d 1362, 1371, 52 USPQ2d 1129, 1135-36 (Fed.Cir.1999) (holding that a reasonable amount of experimentation does not invalidate a patent, but undue experimentation does invalidate, and holding that the *Wands* factors, which determine whether a patent's disclosure is insufficient such that the experimentation required would be undue, apply to inter partes litigation). [FN11] While ultimately a trier of fact may reach the conclusion that any required experimentation is not undue, Crown has shown that sufficient potential for undue experimentation exists such that disposal on summary judgment is improper.

FN10. We note that the specification for the '258 patent states that in the disclosed embodiment the wave index is calculated using a software program running on a personal computer being fed the trace line. '258 patent, col. 7, ll. 64-68. Undoubtedly, Solutia took care to ensure that the program contained the necessary boundary conditions and other information to calculate wave index to practice the invention. It appears, however, that Solutia took substantially less care in transcribing the information from the program into the specification's rules for calculating wave index. This incongruity will be relevant to the question of enablement upon remand. *See* Chisum, § 7.03[4][e] at 7-86 & n. 77 ("A specification that claims an invention requiring implementation through computer software but fails to set forth the details of computer programming may present issues of whether the experimentation required to write the programming is reasonable or unreasonable.") (summarizing the teachings of various cases).

FN11. The *Wands* factors are:
(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed.Cir.1988).

***1382** CONCLUSION

Because we hold that the '511 patent has not been shown to be invalid due to anticipation or obviousness and that a genuine issue of material fact exists with respect to facts underlying the determination of enablement for the ' 258 patent, we affirm-in-part and reverse-in-part the district court's decision and remand for additional proceedings consistent with this opinion.

AFFIRMED-IN-PART, REVERSED-IN-PART, AND REMANDED.

COSTS

Each party bears its own costs.

289 F.3d 1367, 62 U.S.P.Q.2d 1917

END OF DOCUMENT

935 F.2d 1555
59 USLW 2766, 19 U.S.P.Q.2d 1111
(Cite as: 935 F.2d 1555)
<YELLOW FLAG>

United States Court of Appeals,
Federal Circuit.

VAS-CATH INCORPORATED and Gambro, Inc.,
Plaintiffs-Appellees,
v.
Sakharam D. MAHURKAR, and Quinton Instruments Company, Defendants-Appellants.

Nos. 90-1528, 91-1032.

June 7, 1991.
Rehearing Denied July 8, 1991.
Suggestion for Rehearing In Banc Declined July 29, 1991.

Corporation, its licensee and its sublicensee filed suit seeking declaratory judgment that their dual-lumen hemodialysis catheters did not infringe defendant's United States patents. The District Court, 745 F.Supp. 517, Frank H. Easterbrook, Circuit Judge, sitting by designation, held that two of defendant's patents were invalid. Appeal was taken. The Court of Appeals, Rich, Circuit Judge, held that material issues of fact existed as to whether design application's drawings provided "written description" of invention adequate to support claims of invalidated patents.

Reversed and remanded.

West Headnotes

[1] Federal Courts k766
170Bk766

In reviewing district court's grant of summary judgment, appellate court is not bound by district court's holding that no material facts are in dispute; rather, appellate court must make independent determination as to whether standards for summary judgment have been met.

[2] Courts k90(2)
106k90(2)

Decisions of three-judge panel of Federal Circuit cannot overturn prior precedential decisions.

[3] Patents k99
291k99

Statutory requirement that patent specification contain written description of invention is separate and distinct from enablement requirement, and purpose of written description requirement is broader than to merely explain how to make and use invention; rather, applicant must also convey with reasonable clarity to those skilled in the art that, as of filing date sought, he or she was in possession of the invention. 35 U.S.C.A. § 112.

[4] Patents k99
291k99

Drawings alone may be sufficient to satisfy statutory requirement that patent specification include written description of invention, and whether drawings are those of design application or utility application is not determinative. 35 U.S.C.A. § 112.

[5] Patents k99
291k99

When determining whether drawings satisfied statutory requirement that patent specification include written description of patent, district court should not have required that design application drawings describe what was novel or important; there was no legally recognizable or protected essential element, gist or heart of invention in combination patent. 35 U.S.C.A. § 112.

[6] Patents k99
291k99

District court, when determining whether drawings of catheter satisfied statutory requirement that patent specification include written description of invention, erred in taking patentholder's other catheter patents into account, inasmuch as patentholder's later patenting of inventions involving different range limitations was irrelevant to written description issue. 35 U.S.C.A. § 112.

[7] Patents k99
291k99

Sufficiency of application under statute requiring that patent specification include written description of invention must be judged as of filing date. 35 U.S.C.A. § 112.

[8] Patents k99
291k99

District court, when determining whether drawings of catheter in design application sufficed to satisfy statutory requirement that patent specification include written description of invention, erred in applying legal standard that essentially required drawings of design application to necessarily exclude all diameters of catheter's return lumens other than those within claimed range. 35 U.S.C.A. § 112.

[9] Patents k323.2(3)
291k323.2(3)

Expert's declaration regarding what drawings in patent design application conveyed to those skilled in the art, when coupled with nonrefutation thereof, was sufficient to raise genuine issue of material fact precluding summary judgment as to whether utility patents for catheter were entitled to benefit of filing date of patentee's earlier-filed design patent which comprised same drawings as utility patents. 35 U.S.C.A. § 112.

[10] Patents k323.2(3)
291k323.2(3)

Material issues of fact existed as to whether drawings in patent design application provided sufficient written description of invention as required by patent statute, precluding summary judgment on issue of whether claims of utility patents were entitled to benefit of filing date of patentee's earlier- filed design patent application, which comprised same drawings as utility patents. 35 U.S.C.A. § 112.

Patents k328(2)
291k328(2)

4,568,329, 4,692,141. Cited.

***1556** William L. Mentlik, Lerner, David, Littenberg, Krumholz & Mentlik, Westfield, ***1557** N.J., argued, for plaintiffs-appellees. With him on the brief, were Roy H. Wepner, John R. Nelson and Joseph S. Littenberg.

Raymond P. Niro, Niro, Scavone, Haller & Niro, Chicago, Ill., argued, for defendants-appellants. With him on the brief, were Joseph N. Hosteny and John C. Janka. Of Counsel was Michael P. Mazza.

Michael J. Sweedler, Darby & Darby, New York City, represented defendants- appellants, Quinton Instruments Co.

Before RICH, MICHEL and PLAGER, Circuit Judges.

RICH, Circuit Judge.

Sakharam D. Mahurkar and Quinton Instruments Company (collectively Mahurkar) appeal from the September 12, 1990 partial final judgment [FN1] of the United States District Court for the Northern District of Illinois, Easterbrook, J., sitting by designation, in Case No. 88 C 4997. Granting partial summary judgment to Vas-Cath Incorporated and its licensee Gambro, Inc. (collectively Vas-Cath), the district court declared Mahurkar's two United States utility patents Nos. 4,568,329 ('329 patent) and 4,692,141 ('141 patent), titled "Double Lumen Catheter," invalid as anticipated under 35 U.S.C. § 102(b). In reaching its decision, reported at 745 F.Supp. 517, 17 USPQ2d 1353, the district court concluded that none of the twenty-one claims of the two utility patents was entitled, under 35 U.S.C. § 120, to the benefit of the filing date of Mahurkar's earlier-filed United States design patent application Serial No. 356,081 ('081 design application), which comprised the same drawings as the utility patents, because the design application did not provide a "written description of the invention" as required by 35 U.S.C. § 112, first paragraph. We *reverse* the grant of summary judgment with respect to all claims.

> FN1. The district court directed entry of final judgment as to the issue of patent invalidity pursuant to Fed.R.Civ.P. 54(b).

BACKGROUND

Sakharam Mahurkar filed the '081 design application, also titled "Double Lumen Catheter," on March 8, 1982. The application was abandoned on November 30, 1984. Figures 1-6 of the '081

design application are reproduced below.

*1558

Image 1 (5.25 X 1.25) Available for Offline Print

Image 2 (5.25 X 1) Available for Offline Print

Image 3 (0.75 X 1.5) Available for Offline Print

Image 4 (0.75 X 1.5) Available for Offline Print

Image 5 (0.75 X 1.5) Available for Offline Print

Image 6 (3.25 X 1.25) Available for Offline Print

As shown, Mahurkar's catheter comprises er comprises a pair of tubes (lumens) designed to allow blood to be removed from an artery, processed in an apparatus that removes impurities, and returned close to the place of removal. Prior art catheters utilized concentric circular lumens, while Mahurkar's employs joined semi-circular tubes that come to a single tapered tip. Advantageously, the puncture area of Mahurkar's semicircular catheter is 42% less than that of a coaxial catheter carrying the same quantity of blood, and its conical tip yields low rates of injury to the blood. The prior art coaxial catheters are now obsolete; Mahurkar's catheters appear to represent more than half of the world's sales. 745 F.Supp. at 520, 17 USPQ2d at 1353-54.

After filing the '081 design application, Mahurkar also filed a Canadian Industrial Design application comprising the same drawings plus additional textual description. On August 9, 1982, Canadian Industrial Design 50,089 (Canadian '089) issued on that application.

More than one year later, on October 1, 1984, Mahurkar filed the first of two utility patent applications that would give rise to the patents now on appeal. Notably, both utility applications included the same drawings as the '081 design application. [FN2] Serial No. 656,601 ('601 utility application) ***1559** claimed the benefit of the filing date of the '081 design application, having been denominated a "continuation" thereof. In an Office Action mailed June 6, 1985, the Patent and Trademark Office (PTO) examiner noted that "the prior application is a design application," but did not dispute that the '601 application was entitled to its filing date. On January 29, 1986, Mahurkar filed Serial No. 823,592 ('592 utility application), again claiming the benefit of the filing date of the '081 design application (the '592 utility application was denominated a continuation of the '601 utility application). In an office action mailed April 1, 1987, the examiner stated that the '592 utility application was "considered to be fully supported by applicant's parent application SN 356,081 filed March 8, 1982 [the ' 081 design application]." The '601 and '592 utility applications issued in 1986 and 1987, respectively, as the '329 and '141 patents, the subjects of this appeal. The independent claims of both patents are set forth in the Appendix hereto.

> FN2. The utility patent drawings contain additional but minor shading and lead lines and reference numerals not present in the design application drawings.

Vas-Cath sued Mahurkar in June 1988, seeking a declaratory judgment that the catheters it manufactured did not infringe Mahurkar's '329 and '141 utility patents. [FN3] Vas-Cath's complaint alleged, inter alia, that the ' 329 and '141 patents were both invalid as anticipated under 35 U.S.C. § 102(b) by Canadian '089. Vas-Cath's anticipation theory was premised on the argument that the '329 and '141 patents were not entitled under 35 U.S.C. § 120 [FN4] to the filing date of the '081 design application because its drawings did not provide an adequate "written description" of the claimed invention as required by 35 U.S.C. § 112, first paragraph.

> FN3. Vas-Cath's apprehension of suit apparently arose from a 1988 Canadian action instituted by Mahurkar for infringement of Canadian '089.

> FN4. Section 120, titled "Benefit of Earlier Filing Date in the United States," provides (emphasis ours):
> An application for patent for an invention *disclosed in the manner provided by the first paragraph of section 112 of this title* in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the

same effect as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

Mahurkar counterclaimed, alleging infringement. Both parties moved for summary judgment on certain issues, including validity. For purposes of the summary judgment motion, Mahurkar conceded that, if he could not antedate it, Canadian '089 would represent an enabling and thus anticipating § 102(b) reference against the claims of his '329 and '141 utility patents. 745 F.Supp. at 521, 17 USPQ2d at 1355. Vas-Cath conceded that the '081 design drawings *enabled* one skilled in the art to practice the claimed invention within the meaning of 35 U.S.C. § 112, first paragraph. *Id.* Thus, the question before the district court was whether the disclosure of the '081 design application, namely, the drawings without more, adequately meets the "written description" requirement also contained in § 112, first paragraph, so as to entitle Mahurkar to the benefit of the 1982 filing date of the '081 design application for his two utility patents and thereby antedates Canadian ' 089.

Concluding that the drawings do not do so, and that therefore the utility patents are anticipated by Canadian '089, the district court held the '329 and '141 patents wholly invalid under 35 U.S.C. § 102(b), *id.* at 524, 17 USPQ2d at 1358, and subsequently granted Mahurkar's motion for entry of a partial final judgment under Fed.R.Civ.P. 54(b) on the validity issue. This appeal followed.

DISCUSSION

The issue before us is whether the district court erred in concluding, on summary judgment, that the disclosure of the '081 design application does not provide a § 112, first paragraph "written description" adequate to support each of the claims of ***1560** the '329 and '141 patents. If the court so erred as to any of the 21 claims at issue, the admittedly anticipatory disclosure of Canadian '089 will have been antedated (and the basis for the court's grant of summary judgment nullified) as to those claims.

[1] In reviewing the district court's grant of summary judgment, we are not bound by its holding that no material facts are in dispute, and must make an independent determination as to whether the standards for summary judgment have been met. *C.R. Bard, Inc. v. Advanced Cardiovascular Systems,* 911 F.2d 670, 673, 15 USPQ2d 1540, 1542-43 (Fed.Cir.1990). Summary judgment will not lie if the dispute about a material fact is "genuine," that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 248, 106 S.Ct. 2505, 2510, 91 L.Ed.2d 202 (1986).

The "Written Description" Requirement of § 112

The first paragraph of 35 U.S.C. § 112 requires that

> [t]he specification shall contain *a written description of the invention,* and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(Emphasis added). Application of the "written description" requirement, derived from the portion of § 112 emphasized above, is central to resolution of this appeal. The district court, having reviewed this court's decisions on the subject, remarked that "[u]nfortunately, it is not so easy to tell what the law of the Federal Circuit is." 745 F.Supp. at 522, 17 USPQ2d at 1356. Perhaps that is so, and, therefore, before proceeding to the merits, we review the case law development of the "written description" requirement with a view to improving the situation. [FN5]

> FN5. For additional background, *see* Rollins, "35 USC 120--The Description Requirement," 64 *J.Pat.Off.Soc'y* 656 (1982); Walterscheid, "Insufficient Disclosure Rejections (Part III)," 62 *J.Pat.Off.Soc'y* 261 (1980).

The cases indicate that the "written description" requirement most often comes into play where claims not presented in the application when filed are presented thereafter. Alternatively, patent applicants often seek the benefit of the filing date of an earlier-filed foreign or United States application

under 35 U.S.C. § 119 or 35 U.S.C. § 120, respectively, for claims of a later-filed application. The question raised by these situations is most often phrased as whether the application provides "adequate support" for the claim(s) at issue; it has also been analyzed in terms of "new matter" under 35 U.S.C. § 132. The "written description" question similarly arises in the interference context, where the issue is whether the specification of one party to the interference can support the claim(s) corresponding to the count(s) at issue, i.e., whether that party "can make the claim" corresponding to the interference count.

To the uninitiated, it may seem anomalous that the first paragraph of 35 U.S.C. § 112 has been interpreted as requiring a separate "description of the invention," when the invention is, necessarily, the subject matter defined in the *claims* under consideration. *See In re Wright,* 866 F.2d 422, 424, 9 USPQ2d 1649, 1651 (Fed.Cir.1989). One may wonder what purpose a separate "written description" requirement serves, when the second paragraph of § 112 expressly requires that the applicant conclude his specification "with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

One explanation is historical: the "written description" requirement was a part of the patent statutes at a time *before* claims were required. A case in point is *Evans v. Eaton,* 20 U.S. (7 Wheat.) 356, 5 L.Ed. 472 (1822), in which the Supreme Court affirmed the circuit court's decision that the ***1561** plaintiff's patent was "deficient," and that the plaintiff could not recover for infringement thereunder. The patent laws then in effect, namely the Patent Act of 1793, did not require claims, but did require, in its 3d section, that the patent applicant "deliver a written description of his invention, and of the manner of using, or process of compounding, the same, in such full, clear and exact terms, as to distinguish the same from all things before known, and to enable any person skilled in the art or science of which it is a branch, or with which it is most nearly connected, to make, compound and use the same...." *Id.* at 430. In view of this language, the Court concluded that the specification of a patent had two objects, the first of which was "to enable artizans to make and use [the invention]...." *Id.* at 433. The second object of the specification was

> to put the public in possession of what the party claims as his own invention, so as to ascertain if he claims anything that is in common use, or is already known, and to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented. It is, therefore, for the purpose of warning an innocent purchaser, or other person using a machine, of his infringement of the patent; and at the same time, of taking from the inventor the means of practising upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification.

Id. at 434.

A second, policy-based rationale for the inclusion in § 112 of both the first paragraph "written description" and the second paragraph "definiteness" requirements was set forth in *Rengo Co. v. Molins Mach. Co.,* 657 F.2d 535, 551, 211 USPQ 303, 321 (3d Cir.), *cert. denied,* 454 U.S. 1055, 102 S.Ct. 600, 70 L.Ed.2d 591 (1981):

> [T]here is a subtle relationship between the policies underlying the description and definiteness requirements, as the two standards, while complementary, approach a similar problem from different directions. Adequate description of the invention guards against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation. The definiteness requirement shapes the future conduct of persons other than the inventor, by insisting that they receive notice of the scope of the patented device.

With respect to the first paragraph of § 112 the severability of its "written description" provision from its enablement ("make and use") provision was recognized by this court's predecessor, the Court of Customs and Patent Appeals, as early as *In re Ruschig,* 379 F.2d 990, 154 USPQ 118 (CCPA 1967). Although the appellants in that case had presumed that the rejection appealed from was based on the enablement requirement of § 112, *id.* at 995, 154 USPQ at 123, the court disagreed:

> [T]he question is not whether [one skilled in the art] would be so enabled but whether the specification discloses the compound to him, specifically, *as something appellants actually invented....* If [the rejection is] based on section 112, it is on the requirement thereof that "The

specification shall contain a written description *of the invention* * * *." (Emphasis ours.)

Id. at 995-96, 154 USPQ at 123 (first emphasis added). The issue, as the court saw it, was one of fact: "Does the specification convey clearly to those skilled in the art, to whom it is addressed, in any way, the information that appellants invented that specific compound [claimed]?" *Id.* at 996, 154 USPQ at 123.

In a 1971 case again involving chemical subject matter, the court expressly stated that "it is possible for a specification to *enable* the practice of an invention as broadly as it is claimed, and still not *describe* that invention." *In re DiLeone,* 436 F.2d 1404, 1405, 168 USPQ 592, 593 (CCPA 1971) (emphasis added). As an example, the court posited the situation "where the specification discusses *only* compound A ***1562** and contains *no* broadening language of any kind. This might very well enable one skilled in the art to make and use compounds B and C; yet the class consisting of A, B and C has not been described." *Id.* at 1405 n. 1, 168 USPQ 593 n. 1 (emphases in original). *See also In re Ahlbrecht,* 435 F.2d 908, 911, 168 USPQ 293, 296 (CCPA 1971) (although disclosure of parent application may have *enabled* production of claimed esters having 2-12 methylene groups, it only *described* esters having 3-12 methylene groups).

The CCPA also recognized a subtle distinction between a written description adequate to *support* a claim under § 112 and a written description sufficient to *anticipate* its subject matter under § 102(b). The difference between "claim-supporting disclosures" and "claim-anticipating disclosures" was dispositive in *In re Lukach,* 442 F.2d 967, 169 USPQ 795 (CCPA 1971), where the court held that a U.S. "grandparent" application did not sufficiently describe the later-claimed invention, but that the appellant's intervening British application, a counterpart to the U.S. application, anticipated the claimed subject matter. As the court pointed out, "the description of a single embodiment of broadly claimed subject matter constitutes a description of the invention for anticipation purposes ..., whereas the same information in a specification might not alone be enough to provide a description of that invention for purposes of adequate disclosure...." *Id.* at 970, 169 USPQ at 797 (citations omitted).

The purpose and applicability of the "written description" requirement were addressed in *In re Smith and Hubin,* 481 F.2d 910, 178 USPQ 620 (CCPA 1973), where the court stated:

> Satisfaction of the description requirement insures that subject matter presented in the form of a claim subsequent to the filing date of the application was sufficiently disclosed at the time of filing so that the prima facie date of invention can fairly be held to be the filing date of the application. This concept applies whether the case factually arises out of an assertion of entitlement to the filing date of a previously filed application under § 120 ... or arises in the interference context wherein the issue is support for a count in the specification of one or more of the parties ... or arises in an ex parte case involving a single application, but where the claim at issue was filed subsequent to the filing of the application....

Id. at 914, 178 USPQ at 623-24 (citations omitted).

The CCPA's "written description" cases often stressed the fact-specificity of the issue. *See, e.g., In re Wertheim,* 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976) ("The primary consideration is *factual* and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure") (emphasis in original); *In re Smith,* 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) ("Precisely how close the description must come to comply with § 112 must be left to case-by-case development"); *DiLeone,* 436 F.2d at 1405, 168 USPQ at 593 ("What is needed to meet the description requirement will necessarily vary depending on the nature of the invention claimed"). The court even went so far as to state:

> [I]t should be readily apparent from recent decisions of this court involving the question of compliance with the description requirement of § 112 that each case must be decided on its own facts. Thus, the precedential value of cases in this area is extremely limited.

In re Driscoll, 562 F.2d 1245, 1250, 195 USPQ 434, 438 (CCPA 1977).

Since its inception, the Court of Appeals for the Federal Circuit has frequently addressed the "written description" requirement of § 112. [FN6] A fairly uniform standard ***1563** for determining compliance with the "written description" requirement has been maintained throughout: "Although [the applicant] does not have to describe exactly the subject matter claimed, ... the description must clearly allow

persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *In re Gosteli,* 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed.Cir.1989) (citations omitted). "[T]he test for sufficiency of support in a parent application is whether the disclosure of the application relied upon 'reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.' " *Ralston Purina Co. v. Far-Mar-Co, Inc.,* 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed.Cir.1985) (quoting *In re Kaslow,* 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed.Cir.1983)). Our cases also provide that compliance with the "written description" requirement of § 112 is a question of fact, to be reviewed under the clearly erroneous standard. *Gosteli,* 872 F.2d at 1012, 10 USPQ2d at 1618; *Utter v. Hiraga,* 845 F.2d 993, 998, 6 USPQ2d 1709, 1714 (Fed.Cir.1988).

FN6. *See, Chester v. Miller,* 906 F.2d 1574, 15 USPQ2d 1333 (Fed.Cir.1990) (parent application's disclosure of chemical species constituted 102(b) prior art against continuation-in-part (c-i-p) application on appeal, but did not provide sufficient written description to support c-i-p's claims to encompassing genus); *In re Gosteli,* 872 F.2d 1008, 10 USPQ2d 1614 (Fed.Cir.1989) (foreign priority application's disclosure of chemical subgenus was insufficient written description to support genus claims of corresponding U.S. application); *In re Wright,* 866 F.2d 422, 9 USPQ2d 1649 (Fed.Cir.1989) (application in "clear compliance" with § 112 "written description" requirement with respect to claim limitation that microcapsules were "not permanently fixed"); *Utter v. Hiraga,* 845 F.2d 993, 998, 6 USPQ2d 1709, 1714 (Fed.Cir.1988) (holding generic interference count to scroll compressor supported by written description of foreign priority application, the court stated, "A specification may, within the meaning of 35 U.S.C. § 112 ¶ 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses"); *Kennecott Corp. v. Kyocera Int'l, Inc.,* 835 F.2d 1419, 5 USPQ2d 1194 (Fed.Cir.1987) (parent application's lack of express disclosure of inherent "equiaxed microstructure" property did not deprive c-i-p's claims to a sintered ceramic body having said property of the benefit of parent's filing date), *cert. denied,* 486 U.S. 1008, 108 S.Ct. 1735, 100 L.Ed.2d 198 (1988); *Ralston Purina Co. v. Far-Mar-Co, Inc.,* 772 F.2d 1570, 227 USPQ 177 (1985) (parent application's disclosure provided adequate written description support for certain claim limitations respecting protein content, temperature, and moisture content, but not others); *In re Wilder,* 736 F.2d 1516, 222 USPQ 369 (1984) (broadly worded title, general description of drawing, and objects of invention of parent patent application did not adequately support reissue application claims directed to genus of indicating mechanisms for dictating machines), *cert. denied,* 469 U.S. 1209, 105 S.Ct. 1173, 84 L.Ed.2d 323 (1985); *In re Kaslow,* 707 F.2d 1366, 217 USPQ 1089 (Fed.Cir.1983) (claims to method of redeeming merchandise coupons, comprising step of providing an audit of coupon traffic, were not supported by specification of parent application).

There appears to be some confusion in our decisions concerning the extent to which the "written description" requirement is separate and distinct from the enablement requirement. For example, in *In re Wilder,* 736 F.2d 1516, 1520, 222 USPQ 369, 372 (Fed.Cir.1984), *cert. denied,* 469 U.S. 1209, 105 S.Ct. 1173, 84 L.Ed.2d 323 (1985), we flatly stated: "The description requirement is found in 35 U.S.C. § 112 and is separate from the enablement requirement of that provision." However, in a later case we said, "The purpose of the [written] description requirement [of section 112, first paragraph] is to state what is needed to fulfill the enablement criteria. These requirements may be viewed separately, but they are intertwined." *Kennecott Corp. v. Kyocera Int'l, Inc.,* 835 F.2d 1419, 1421, 5 USPQ2d 1194, 1197 (Fed.Cir.1987), *cert. denied,* 486 U.S. 1008, 108 S.Ct. 1735, 100 L.Ed.2d 198 (1988). "The written description must communicate that which is needed to enable the skilled artisan to make and use the claimed invention." *Id.*

[2][3] To the extent that *Kennecott* conflicts with *Wilder,* we note that decisions of a three-judge panel of this court cannot overturn prior precedential decisions. *See UMC Elec. Co. v. United States,*

816 F.2d 647, 652 n. 6, 2 USPQ2d 1465, 1468 n. 7 (Fed.Cir.1987), *cert. denied,* 484 U.S. 1025, 108 S.Ct. 748, 98 L.Ed.2d 761 (1988). This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 U.S.C. § 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date ***1564** sought, he or she was in possession *of the invention.* The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

The District Court's Analysis

[4] We agree with the district court's conclusion that drawings alone *may* be sufficient to provide the "written description of the invention" required by § 112, first paragraph. Several earlier cases, though not specifically framing the issue in terms of compliance with the "written description" requirement, support this conclusion.

For example, we previously stated that "[t]here is no statutory prohibition against an applicant's reliance, in claiming priority under 35 U.S.C. § 120, on a disclosure in a design application if the statutory conditions are met." *KangaROOS U.S.A., Inc. v. Caldor, Inc.,* 778 F.2d 1571, 1574, 228 USPQ 32, 33 (Fed.Cir.1985). The question whether the applicant's claim to a pocket for athletic shoes was in fact entitled to the filing date of his earlier design application was not resolved in *KangaROOS,* however. Issues of intent to deceive the PTO were involved, as well as an error of law by the district court in construing the claims of the wrong application. *Id.* at 1574-75, 228 USPQ at 34-35. The district court's grant of partial summary judgment of inequitable conduct was vacated and the case remanded for trial.

In re Berkman, 642 F.2d 427, 209 USPQ 45 (CCPA 1981) involved a claim under 35 U.S.C. § 120 to the benefit of the filing date of two earlier design patent applications that included drawings of a carrying and storage case for tape cartridges and cassettes. The invention claimed in the later- filed utility application was an "insert" of "compartmented form," adapted for use in the interior of the storage case. *Id.* at 429, 209 USPQ at 47. The court characterized the dispositive issue as "whether the design applications sufficiently disclose the invention now claimed in the ... utility application at bar." *Id.* at 429, 209 USPQ at 46. While specifically recognizing that "drawings may be used to satisfy the disclosure requirement," *id.* at 429, 209 USPQ at 46-47, the court held that Berkman's design applications "fail[ed] to disclose the claimed invention sufficiently to comply with the requirements of § 112 first paragraph." As the court explained:

> Nowhere in the design applications is the word "insert" used, nor is there any indication that the interiors of the cases are inserts. The drawings do not disclose how the insert can be used to accommodate either cassette or cartridge type tape enclosures. Berkman argues that one skilled in the art would readily recognize that the interiors of the cases illustrated in the design drawings are inserts. We do not agree. There is nothing shown in the drawings to lead one of ordinary skill to such a conclusion.

Id. at 430, 209 USPQ at 47.

The issue in *In re Wolfensperger,* 49 CCPA 1075, 302 F.2d 950, 133 USPQ 537 (1962) was whether the specification of the applicant's utility patent application disclosing a ball valve, and particularly the drawings thereof, supported a claim limitation that read: "having, in untensioned condition, a mean diameter corresponding approximately to the mean diameter of said chamber and a radial width smaller than the radial width of said chamber...." *Id.* at 1077, 302 F.2d at 952, 133 USPQ at 538. The court did not agree with the Board's conclusion that the "radial width" relationship was not supported by applicant's figure 5:

> The board's statement that "drawings alone cannot form the basis of a valid claim" is too broad a generalization to be valid and is, furthermore, contrary to well-settled and long-established Patent Office practice.... Consider, for one thing, that the sole disclosure in a design patent application is by means of a drawing.... For another thing, consider that the only informative and significant disclosure in many electrical and chemical patents is by means of circuit diagrams or graphic formulae, constituting "drawings" in the case....
>
> ... The practical, legitimate enquiry in each case of this kind is what the drawing in fact discloses to one skilled in the art....
>
> ***1565** ... The issue here is whether there is supporting "disclosure" and it does not seem,

under established procedure of long standing, approved by this court, to be of any legal significance whether the disclosure is found in the specification or in the drawings so long as it is there.

Id. at 1080-83, 302 F.2d at 955-56, 133 USPQ at 541-42.

Employing a "new matter" analysis, the court in *In re Heinle,* 342 F.2d 1001, 145 USPQ 131 (CCPA 1965) reversed a PTO rejection of the applicant's claims to a "toilet paper core" as "including subject matter having no clear basis in the application as filed." *Id.* at 1003, 145 USPQ at 133. The claim limitation said to be without support required that the width of the apertures in the core be "approximately one-fourth of the circumference of said core." *Id.* at 1007, 145 USPQ at 136. Having reviewed the application drawings relied upon for support, the court stated:

> it seems to us that [the drawings] conform to the one-fourth circumference limitation almost exactly. But the claim requires only an approximation. Since we believe an amendment to the specification to state that one-fourth of the circumference is the aperture width would not violate the rule against "new matter," we feel that supporting disclosure exists. The rejection is therefore in error.

Id.

These cases support our holding that, under proper circumstances, drawings alone may provide a "written description" of an invention as required by § 112. Whether the drawings are those of a design application or a utility application is not determinative, although in most cases the latter are much more detailed. In the instant case, however, the design drawings are substantially identical to the utility application drawings.

[5] Although we join with the district court in concluding that drawings may suffice to satisfy the "written description" requirement of § 112, we can not agree with the legal standard that the court imposed for "written description" compliance, nor with the court's conclusion that no genuine issues of material fact were in dispute.

With respect to the former, the district court stated that although the '081 design drawings in question "allowed practice" [i.e., enabled], they did not necessarily

> show what the invention is, when "the invention" could be a subset or a superset of the features shown. Is the invention the semi-circular lumens? The conical tip? The ratio at which the tip tapers? The shape, size, and placement of the inlets and outlets? You can measure all of these things from the diagrams in serial '081 and so can practice the device, but you cannot tell, because serial '081 does not say, what combination of these things is "the invention", and what range of variation is allowed without exceeding the scope of the claims. To show one example of an invention, even a working model, is not to describe what is novel or important.

745 F.Supp. at 522, 17 USPQ2d at 1356.

We find the district court's concern with "what the invention is" misplaced, and its requirement that the '081 drawings "describe what is novel or important" legal error. There is "no legally recognizable or protected 'essential' element, 'gist' or 'heart' of the invention in a combination patent." *Aro Mfg. Co. v. Convertible Top Replacement Co.,* 365 U.S. 336, 345, 81 S.Ct. 599, 604, 5 L.Ed.2d 592 (1961). "The invention" is defined by the claims on appeal. The instant claims do not recite *only* a pair of semi-circular lumens, or a conical tip, or a ratio at which the tip tapers, or the shape, size, and placement of the inlets and outlets; they claim *a double lumen catheter* having a *combination* of those features. That combination invention *is* what the '081 drawings show. As the district court itself recognized, "what Mahurkar eventually patented is exactly what the pictures in serial '081 show." 745 F.Supp. at 523, 17 USPQ2d at 1357.

We find the "range of variation" question, much emphasized by the parties, more troublesome. The district court stated that "although Mahurkar's patents use the same diagrams, [the claims] contain limitations ***1566** that did not follow ineluctably [i.e., inevitably] from the diagrams." *Id.* at 524, 17 USPQ2d at 1357. As an example, the court stated (presumably with respect to independent claims 1 and 7 of the '329 patent) that

> the utility patents claim a return lumen that is "substantially greater than one-half but substantially less than a full diameter" after it makes the transition from semi-circular to circular cross-section, and the drawings of serial '081 fall in this range. But until the utility application was filed, nothing established that they had to--for that matter that the utility patent would claim anything other than the *precise* ratio in the diagrams....

Id. at 523, 17 USPQ2d at 1357. Mahurkar argues

that one of ordinary skill in this art, looking at the '081 drawings, would be able to derive the claimed range.

The declaration of Dr. Stephen Ash, submitted by Mahurkar, is directed to these concerns. Dr. Ash, a physician specializing in nephrology (the study of the kidney and its diseases) and chairman of a corporation that develops and manufactures biomedical devices including catheters, explains why one of skill in the art of catheter design and manufacture, studying the drawings of the '081 application in early 1982, would have understood from them that the return lumen must have a diameter within the range recited by independent claims 1 and 7 of the '329 patent. Dr. Ash explains in detail that a return (longer) lumen of diameter less than half that of the two lumens combined would produce too great a pressure increase, while a return lumen of diameter equal or larger than that of the two lumens combined would result in too great a pressure drop. [FN7] "Ordinary experience with the flow of blood in catheters would lead directly away from any such arrangement," Ash states.

> FN7. Higher pressure drops are associated with smaller cross- sectional areas for fluid flow. Mahurkar's opening brief to this court states that by applying well-known principles of fluid mechanics (i.e., the work of Poiseuille and Hagen), it can be calculated that the diameter of the circular (return) lumen would have to be in the range of 0.66 times the diameter of the two lumens combined in order to achieve proper blood flow at equal pressure drop. The 0.66 ratio falls within the noted claim limitation.

Although the district court found this reasoning "logical," it noted that later patents issued to Mahurkar disclose diameter ratios closer to 1.0 (U.S.Patent No. 4,584,968) and exactly 0.5 (U.S.Des.Patent No. 272,651). If these other ratios were desirable, the district court queried, "how does serial '081 necessarily exclude the[m]?" 745 F.Supp. at 523, 17 USPQ2d at 1357.

[6][7] The district court erred in taking Mahurkar's other patents into account. Mahurkar's *later* patenting of inventions involving different range limitations is irrelevant to the issue at hand. Application sufficiency under § 112, first paragraph, must be judged as of the filing date. *United States Steel Corp. v. Phillips Petroleum Co.,* 865 F.2d 1247, 1251, 9 USPQ2d 1461, 1464 (Fed.Cir.1989).

[8] The court further erred in applying a legal standard that essentially required the drawings of the '081 design application to *necessarily exclude* all diameters other than those within the claimed range. We question whether any drawing could ever do so. At least with respect to independent claims 1 and 7 of the '329 patent and claims depending therefrom, the proper test is whether the drawings conveyed with reasonable clarity to those of ordinary skill that Mahurkar had in fact invented the catheter recited in those claims, having (among several other limitations) a return lumen diameter substantially less than 1.0 but substantially greater than 0.5 times the diameter of the combined lumens. Consideration of what the drawings conveyed to persons of ordinary skill is essential. *See Ralston Purina,* 772 F.2d at 1575, 227 USPQ at 179 (ranges found in applicant's claims need not correspond *exactly* to those disclosed in parent application; issue is whether one skilled in the art could derive the claimed ranges from parent's disclosure).

[9][10] ***1567** Mahurkar submitted the declaration of Dr. Ash on this point; Vas-Cath submitted no technical evidence to refute Ash's conclusions. Although the district court considered Dr. Ash's declaration, we believe its import was improperly disregarded when viewed through the court's erroneous interpretation of the law. [FN8] We hold that the Ash declaration and Vas- Cath's non-refutation thereof, without more, gave rise to a genuine issue of material fact inappropriate for summary disposition. *See Hesston Corp. v. Sloop,* 1988 U.S.Dist. LEXIS 1573, *13 (D.Kansas) (summary judgment on § 112 "written description" issue inappropriate where resolution of what parent disclosure conveyed to those skilled in the art may require examination of experts, demonstrations and exhibits).

> FN8. The following colloquy at oral argument before the district court supports our view:
> *Counsel for Mahurkar:* "So the only evidence that we have on this subject from people of ordinary skill in the art is that the drawings do communicate these range limitations, and given the procedural posture of this case, the Court has to accept that evidence...."
> *District Court:* * * * "And if you could

> have written a large number of things that were different from what was actually filed in 1984, then the diagram isn't enough. And that seems to me something that can't be resolved by ogling the Ash declaration. It's really a pure question of law."

Mahurkar urges that at least some of the remaining claims do not contain the range limitations discussed by the district court, and that the presence of range limitations was not a proper basis for invalidating those remaining claims. For example, claim 8 of the '141 patent requires, inter alia, a smooth conical tapered tip and "the portion of said tube between said second opening and said conical tapered tip *being larger than* said first lumen in the transverse direction normal to the plane of said septum." Vas-Cath counters that claim 8 of the '141 patent is just as much a "range" claim as claims 1 and 7 of the '329 patent, albeit one having only a lower limit and no upper limit.

Absent any separate discussion of these remaining claims in the district court's opinion, we assume that the court applied to them the same erroneous legal standard. Summary judgment was therefore inappropriate as to the remaining claims. Additionally, the possibility that the '081 drawings may provide an adequate § 112 "written description" of the subject matter of some of the claims but not others should have been considered. *See, e.g., In re Borkowski,* 422 F.2d 904, 909 n. 4, 164 USPQ 642, 646 n. 4 (CCPA 1970) (on review of § 112 non-enablement rejection: "A disclosure may, of course, be insufficient to support one claim but sufficient to support another.") On remand, the district court should *separately* analyze whether the "written description" requirement has been met as to the subject matter of *each* claim of the '141 and '329 patents.

CONCLUSION

The district court's grant of summary judgment, holding all claims of the '329 and '141 patents invalid under 35 U.S.C. § 102(b), is hereby reversed as to all claims, and the case remanded for further proceedings consistent herewith.

COSTS

Each party to bear its own costs.

REVERSED and REMANDED.

APPENDIX

Independent Claims of the '329 Patent:

1. A double lumen catheter having an elongated tube with a proximal first cylindrical portion enclosing first and second lumens separated by an internal divider, the proximal end of said elongated tube connecting to two separate connecting tubes communicating with the respective first and second lumens for the injection and removal of fluid, the first lumen extending from the proximal end of said elongated tube to a first opening at the distal end of said elongated tube, and the second lumen extending from the proximal end of said elongated tube to a second opening at approximately the distal ***1568** end of said first cylindrical portion, wherein the improvement comprises:

said elongated tube having at its distal end a smooth conical tapered tip that smoothly merges with a second cylindrical portion of said elongated tube, and said second cylindrical portion enclosing the first lumen from the conical tapered tip to approximately the location of said second opening, wherein said second cylindrical portion has a diameter substantially greater than one-half but substantially less than a full diameter of said first cylindrical portion.

7. A double lumen catheter having an elongated tube with a proximal first cylindrical portion enclosing first and second lumens separated by an internal divider, the proximal end of said elongated tube connecting to two separate connecting tubes communicating with the respective first and second lumens for the injection and removal of fluid, the first lumen extending from the proximal end of said elongated tube to a first opening at the distal end of said elongated tube, and the second lumen extending from the proximal end of said elongated tube to a second opening at approximately the distal end of said first cylindrical portion, wherein the improvement comprises:

said elongated tube having at its distal end a smooth conical tapered tip that smoothly merges with a second cylindrical portion of said elongated tube, and said second cylindrical portion enclosing the first lumen from the conical tapered tip to approximately the location of said second opening, said second cylindrical portion having a diameter substantially greater than one-half but substantially less than a full diameter of said first cylindrical portion, said divider in said first cylindrical portion being planar, the lumens being

"D" shaped in cross-section in said first cylindrical portion, the elongated tube being provided with a plurality of holes in the region of the conical tapered tip, and said first cylindrical portion of the elongated tube smoothly merging with said second cylindrical portion of the elongated tube.

Independent Claims of the '141 Patent:

1. A double lumen catheter having an elongated tube with a proximal first cylindrical portion enclosing first and second lumens separated by an internal divider, the proximal end of said elongated tube connecting to two separate connecting tubes communicating with the respective first and second lumens for the injection and removal of fluid, the first lumen extending from the proximal end of said elongated tube to a first opening at the distal end of said elongated tube, and the second lumen extending from the proximal end of said elongated tube to a second opening at approximately the distal end of said first cylindrical portion, wherein the improvement comprises:

said elongated tube having at its distal end a smooth conical tapered tip that smoothly merges with a second cylindrical portion of said elongated tube, and said second cylindrical portion enclosing the first lumen from the conical tapered tip to approximately the location of said second opening, wherein said second sylindrical [sic] portion has a diameter substantially less than a full diameter of said first cylindrical portion but larger than said first lumen in the transverse direction normal to the plane of said flat divider.

7. A double lumen catheter comprising an elongated cylindrical tube enclosing first and second lumens separated by a flat longitudinal internal divider formed as an integral part of said tube, said tube and said divider forming said first and second lumens as semi-cylindrical cavities within said tube, the proximal end of said elongated tube connecting to two separate connecting tubes communicating with the respective first and second lumens for the injection and removal of fluid, the first lumen extending from the proximal end of said elongated tube to a first opening at the distal end of said ***1569** elongated tube, said distal end of said tube forming a smooth conical tapered tip and the second lumen extending from the proximal end of said elongated tube to a second opening spaced a substantial distance away from said first opening toward the proximal end of said tube, the distal end of said divider being joined to the outside wall of said tube distal of said second opening, and the outside wall of said tube forming a smooth transition between said conical tapered tip and the outer circumference of the tube proximal of said second opening, said transition being larger than said first lumen in the transverse direction normal to the plane of said flat divider.

8. A double lumen catheter comprising an elongated cylindrical tube having a longitudinal planar septum of one-piece construction with said tube, said septum dividing the interior of said tube into first and second lumens, said lumens being D-shaped in cross-section, the proximal end of said tube connecting to two separate tubes communicating with the respective first and second lumens for the injection and removal of fluids, the lumen extending from the proximal end of said tube to a first lumen extending from the proximal end of said tube to a first opening at the distal end of said tube, and the second lumen extending from the proximal end of said tube to a second opening axially spaced from the distal end of said tube, said tube having at its distal end a smooth conical tapered tip that merges with the cylindrical surface of said tube, said first lumen, including the internal wall thereof formed by said septum extending continuously through said conical tapered tip, and the portion of said tube between said second opening and said conical tapered tip being larger than said first lumen in the transverse direction normal to the plane of said septum.

13. A double lumen catheter comprising an elongated cylindrical tube enclosing first and second lumens separated by a flat longitudinal internal divider formed as an integral part of said tube, said tube and said divider forming said first and second lumens as semi-cylindrical cavities within said tube, the proximal end of said elongated tube connecting to two separate connecting tubes communicating with he [sic] respective first and second lumens for the injection and removal of fluid, the first lumen extending from the proximal end of said elongated tube to a first opening at the distal end of said elongated tube, said distal end of said tube forming a smooth conical tapered tip defining the distal portion of said first lumen and said first opening, said first opening and an adjacent portion of said first lumen having a circular transverse cross-sectional configuration, and the second lumen extending from the proximal end of said elongated tube to a second opening spaced a

substantial distance away from said first opening toward the proximal end of said tube, the inside walls of said tube forming a smooth transition between said semicylindrical and circular transverse cross-sectional configurations of said first lumen, the outside dimension of said transition being larger than said first lumen in the transverse direction normal to the plane of said flat divider.

935 F.2d 1555, 59 USLW 2766, 19 U.S.P.Q.2d 1111

END OF DOCUMENT

558 F.2d 1008
194 U.S.P.Q. 187
(Cite as: 558 F.2d 1008)
<KeyCite Citations>
United States Court of Customs and Patent Appeals.

Application of Robert N. JOHNSON and Alford G. Farnham.

Patent Appeal No. 76-643.

June 16, 1977.

The Patent and Trademark Office Board of Appeals affirmed rejection of various claims in application, Serial No. 230,091, for "Polyarylene Polyethers," and appeal was taken. The Court of Customs and Patent Appeals, Markey, C. J., held that: (1) subject matter embraced by certain claims was definite and claims set out and circumscribed particular area with reasonable degree of precision and particularity; (2) claims were improperly rejected as broader than the enabling disclosure; (3) fact that applicant deleted certain compounds from protection sought and claimed less than full scope of disclosure did not render application insufficient under statute relating to specification.

Reversed.

Lane, J., dissented in part and filed opinion.

West Headnotes

[1] Patents k101(6)
291k101(6)

Under statute providing that specification shall conclude with one or more claims particularly pointing out and distinctly claiming subject matter which the applicant regards as his invention, inquiry is whether claims do, in fact, set out and circumscribe particular area with reasonable degree of precision and particularity; definiteness of language employed must be analyzed, not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art. 35 U.S.C.A. § 112.

[2] Patents k99
291k99

For purpose of statute relating to specification, undue breadth is not "indefiniteness." 35 U.S.C.A. § 112.

[3] Patents k101(4)
291k101(4)

Claim language must be read in light of the specification as it would be interpreted by one of ordinary skill in the art. 35 U.S.C.A. § 112.

[4] Patents k101(5)
291k101(5)

Subject matter embraced by claims relating to polyarylene polyether polymers set out and circumscribed particular area with reasonable degree of precision and particularity, and thus rejection of claims under statute requiring specification to conclude with one or more claims particularly pointing out and distinctly claiming subject matter which applicant regarded as his invention was unwarranted. 35 U.S.C.A. § 112.

[5] Patents k99
291k99

[5] Patents k101(1)
291k101(1)

It is the function of the specification, not the claims, to set forth the practical limits of operation of an invention; one does not look to the claims to find out how to practice the invention they define, but to the specifications. 35 U.S.C.A. § 112.

[6] Patents k101(3)
291k101(3)

Specification as a whole must be considered in determining whether scope of enablement provided by specification is commensurate with scope of the claims. 35 U.S.C.A. § 112.

[7] Patents k101(5)
291k101(5)

To provide effective incentives, claims must adequately protect inventors; to demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process would not serve constitutional purpose of promoting the progress in the useful arts. 35 U.S.C.A. § 112.

[8] Patents k99
291k99

For purpose of claims relating to polyarylene polyether polymers, specification satisfied statutory requirements that specification contain concise written description of invention so as to enable any person skilled in the art to make and use the invention and that specification set forth best mode contemplated by inventor of carrying out his invention. 35 U.S.C.A. § 112.

[9] Patents k109
291k109

Fact that applicants excluded from original claims two species specifically disclosed in 1963 application did not render disclosure insufficient, under statute relating to specification, for "limited genus" claim where claim was otherwise entitled to benefit of 1963 filing date and where applicants had merely narrowed their claims to avoid having them read on a lost interference count. 35 U.S.C.A. § 112.

[10] Patents k98
291k98

It is for the inventor to decide what bounds of protection he will seek. 35 U.S.C.A. § 112.

***1009** Robert C. Brown, New York City, Aldo J. Cozzi, Union City, N. J., attorneys of record, for appellants; James C. Arvantes, Arlington, Va., of counsel.

Joseph F. Nakamura, Washington, D. C., for the Commissioner of Patents; Henry W. Tarring, II, Washington, D. C., of counsel.

Before MARKEY, Chief Judge, and RICH, BALDWIN, LANE and MILLER, Judges.

MARKEY, Chief Judge.

This appeal is from the decision of the Patent and Trademark Office (PTO) Board of Appeals affirming the rejection under 35 U.S.C. ss 102 or 103 (the rejection also raises a written description issue under 35 U.S.C. s 112, first paragraph) of claims 1-9, 64, and 68-70 and the rejection under 35 U.S.C. s 112, first paragraph (enablement) and second paragraph (indefiniteness), of claims 64 and 68-72 in appellants' application No. 230,091 filed February 28, 1972 (the 1972 application) for "Polyarylene Polyethers." [FN1] The 1972 application is a continuation-in-part of three earlier applications, the earliest being application No. 295,519 filed July 16, 1963 (the 1963 application). We reverse.

FN1. Claims 10-54 and 65-67 stand allowed. A petition for reconsideration was denied by the board.

The Invention

The invention is in the field of polymer chemistry and more specifically relates to linear thermoplastic polyarylene polyether polymers composed of recurring units having the general formula O-E-O-E' where O represents an oxygen atom, [FN2] E represents the residuum of a dihydric phenol [FN3] compound, and E' represents the residuum ***1010** of a benzenoid compound having one or more inert electron withdrawing groups [FN4] in the ortho [FN5] or para [FN6] positions to the valence bonds and where both E and E' are bonded to the ether oxygens through aromatic carbon atoms.

FN2. The -O- linkages in the general formula are called ether linkages.

FN3. A dihydric phenol is a type of aromatic organic compound in which two hydroxy (-OH) groups are attached directly to a benzene ring.

FN4. An electron withdrawing group is a substituent which withdraws electrons from the aromatic ring to which it is attached.

FN5. An aromatic ring bearing substituents on adjacent carbon atoms is called ortho substituted.

FN6. An aromatic ring bearing substituents

on opposite carbon atoms is called para substituted.

Appellants describe a method of synthesizing these polymers by reacting a double alkali metal salt of a dihydric phenol with a dihalobenzenoid compound in the presence of certain solvents under substantially anhydrous reaction conditions.

The 1972 application includes the following disclosure with respect to the electron withdrawing group found in E' and in the E' precursor compound, that is, in the compound which is the predecessor of E' in the above general formula (we have designated paragraphs (A) and (B) and have added emphasis thereto):

> Any electron withdrawing group can be employed as the activator group in these compounds. It should be, of course, inert to the reaction, but otherwise its structure is not critical. Preferred are the strong activating groups such as the sulfone group
>
> Image 1 (0.75 X 0.5) Available for Offline Print
>
> bonding two halogon substituted benzenoid nuclei as in the 4,4'- dichlorodiphenyl sulfone and 4,4'-difluorodiphenyl sulfone, although such other strong withdrawing groups hereinafter mentioned can also be used with equal ease.

The more powerful of the electron withdrawing groups give the fastest reactions and hence are preferred. It is further preferred that the ring contain no electron supplying groups on the same benzenoid nucleus as the halogen; however, the presence of other groups on the nucleus or in the residuum of the compound can be tolerated. Preferably, all of the substituents on the benzenoid nucleus are either hydrogen (zero electron withdrawing), or other groups having a positive sigma * value, as set forth in J.F. Bunnett in Chem.Rev. 49 273 (1951) and Quart.Rev., 12, 1 (1958). See also Taft, Steric Effects in Organic Chemistry, John Wiley & Sons (1956), chapter 13; Chem.Rev., 53, 222; JACS, 74, 3120; and JACS, 75, 4231. [FN7]

> FN7. Appellants' brief specifically refers to one of the publications cited (Chem.Rev., 53, 222 (1953)) and states that its author (Jaffe) defines the sigma * value as a "special substituent constant" for the "Hammett equation" which is an empirically derived formula intended to show a general quantitative relation between the nature of a given substituent and the reactivity of a side chain. Thus, sigma * values are based on experimental data and they measure the "activation energy" of a given substituent (electron withdrawing group).

The electron withdrawing group of the dihalobenzenoid compound can function either through the resonance of the aromatic ring, as indicated by those groups having a high sigma * value, i.e., above about k0.7 or by induction as in perfluoro compounds and like electron sinks.

(A)

Preferably the activating group should have a high sigma * value, preferably above 1.0, although sufficient activity to promote the reaction is evidenced in those groups having a sigma value above 0.7, although the reaction rate with such a low powered electron withdrawing group may be somewhat low.

The activating group can be basically either of two types:

(a) monovalent groups that activate one or more halogens on the same ring as a nitro group, phenylsulfone, or alkylsulfone, cyano, trifluoromethyl, nitroso, and hetero nitrogen as in pyridine.

***1011** (b) divalent group (sic) which can activate displacement of halogens on two different rings, such as the sulfone group

Image 2 (0.75 X 0.5) Available for Offline Print

; the carbonyl group

Image 3 (0.5 X 0.5) Available for Offline Print

; the vinyl group

Image 4 (0.75 X 0.75) Available for Offline Print

; the sulfoxide group

Image 5 (0.5 X 0.5) Available for Offline Print

; the azo-group-N = N-; the saturated fluorocarbon groups -CF sub2 CF sub2 -; organic phosphine oxides

Image 6 (0.75 X 0.5) Available for Offline Print

; where R is a hydrocarbon group, and the ethylidene group

Image 7 (0.5 X 0.75) Available for Offline Print

where X can be hydrogen or halogen or which can activate halogens on the same ring such as with difluorobenzoquinone, 1,- 4- or 1,5- or 1,8-difluoroanthranquinone.

(B)

Those skilled in the art will understand that a plurality of electron withdrawing groups may be employed if desired, including electron withdrawing groups having a sigma * value below about k0.7 provided the cumulative sigma * influence on each of the reactive halogen groups of the halobenzenoid compound is at least about k0.7.

The Disclosure and Prosecution History of the 1963 Application

To understand the written description issue in this appeal, it is necessary to summarize the disclosure and prosecution history of the 1963 application. The 1963 application described (and claimed) in haec verba a genus of polymers as defined by the above general formula. That application stated:

The high molecular weight polyarylene polyethers of the present invention are the linear thermoplastic reaction products of an alkali metal double salt of a dihydric phenol and a dihalobenzenoid compound. Characteristically, this polymer has a basic structure composed of recurring units having the formula

-O-E-O-E'-

wherein E is the residuum of the dihydric phenol and E' is the residuum of the benzenoid compound, both of which are valently bonded to the ether oxygen through aromatic carbon atoms, as hereinafter more fully discussed. Polymers of this type exhibit excellent strength and toughness properties as well as outstanding thermal, oxidative and chemical stability.

The 1963 application then discussed the identity of E and the E' precursor compound, that is, the compound which is the predecessor of E in the general formula. It stated:

The residuum E of the dihydric phenol of these alkali metal salts is not narrowly critical. It can be, for instance, a mononuclear phenylene group as results from hydroquinone and resorcinol, or it may be a di- or polynuclear residuum. Likewise it is possible that the residuum be substituted with other inert nuclear substituents such as halogen, alkyl, alkoxy and like inert substituents.

* * *

Such dinuclear phenols can be characterized as having the structure:

Image 8 (0.5 X 1.25) Available for Offline Print

wherein Ar is an aromatic group and preferably is a phenylene group, Y and Y sub1 can be the same or different inert substituent groups as alkyl groups having from 1 to 4 carbon atoms, halogen atoms, i. e. fluorine, chlorine, bromine or iodine, or alkoxy radicals having from 1 to 4 carbon atoms, r and z are integers having a value from 0 to 4, inclusive, and R is representative of a bond between aromatic carbon atoms as in dihydroxydiphenyl, or is a divalent radical, including for example, inorganic radicals as

Image 9 (0.5 X 0.5) Available for Offline Print

,-O-, -S-, -S-S-, -SO2-, and divalent organic hydrocarbon radicals such as alkylene, alkylidene, cycloaliphatic, or the

***1012** halogen, alkyl, aryl or like substituted alkylene, alkylidene and cycloaliphatic radicals as well as alkalicyclic, alkarylene and aromatic radicals and a ring fused to both Ar group[s].

The application then mentioned by name some fifty specific dihydric dinuclear phenol (bisphenol) compounds which could be the E precursor compound. The application further stated:

A preferred form of the polyarylene polyethers of this invention are those prepared using the

dihydric polynuclear phenols of the following four types, including the derivatives thereof which are substituted with inert substituent groups

Image 10 (0.75▒ X 2.75▒) Available for Offline Print

in which the R group represents hydrogen, lower alkyl, lower aryl and the halogen substituted groups thereof, which can be the same or different.

Image 11 (1.75▒ X 2.75▒) Available for Offline Print

Turning to the identity of the E' precursor compound, the application stated:

Any dihalobenzenoid compound or mixture of dihalobenzenoid compounds can be employed in this invention which compound or compounds has the two halogens bonded to benzene rings having an electron withdrawing group in at least one of the positions ortho and para to the halogen group. The dihalobenzenoid compound can be either mononuclear where the halogens are attached to the same benzenoid ring or polynuclear where they are attached to different benzenoid rings, as long as there is the activating electron withdrawing group in the ortho or para position of that benzenoid nucleus.

The 1963 application also included a discussion of the electron withdrawing group that was substantially the same as the paragraphs quoted above from the 1972 application.

The 1963 application contained twenty-six "examples" disclosing in detail the physical and chemical characteristics of fifteen species of polyarylene polyethers. One of the species was the polymer composed of these recurring structural units (which we designate as species (1)): [FN8]

FN8. The -SO 2- linking group in species (1) is called a sulfone group.

Image 12 (1.25▒ X 2.5▒) Available for Offline Print

Another species disclosed was the polymer composed of these recurring structural units (which we designate as species (2)): [FN9]

FN9. The -CO- linking group in species (2) is called a carbonyl group.

Image 13 (1▒ X 2.5▒) Available for Offline Print

Appellants' 1963 application became involved in a three-party interference [FN10] which resulted in an award of priority adverse to appellants from which they did not appeal. [FN11] The sole count of the interference recited species (1).

FN10. Interference No. 95,807, declared February 17, 1967.

FN11. Another party did appeal. See Vogel v. Jones, 486 F.2d 1068, 179 USPQ 425 (Cust. & Pat.App.1973).

***1013** After their involvement in the interference ended, appellants filed the 1972 application, and they sought broad claims which would at the same time exclude the subject matter of the lost count.

The Claims

Claim 1, now on appeal, is illustrative of the group of claims (claims 1-9, 64, and 68-70) which seek to exclude the subject matter of the lost count and which are involved in the 35 U.S.C. ss 102 or 103 rejection:

1. A substantially linear thermoplastic polyarylene polyether composed of recurring units having the general formula:
-(O-E-O-E')-
where E is the residuum of a dihydric phenol and E' is the residuum of a benzenoid compound having an inert electron withdrawing group in one or more of the positions ortho and para to the valence bonds having a sigma * value above about k0.7, and where both of said residuum (sic, residua) are valently bonded to the ether oxygens through aromatic carbon atoms with the provisos that E and E' may not both include a divalent sulfone group and may not both include a divalent carbonyl group linking two aromatic nuclei. (Emphasis added.)

The first "proviso" in claim 1, that "E and E' may not both include a divalent sulfone group," excludes species (1), the species of the lost count. The second "proviso," that "E and E' * * * may not both include a divalent carbonyl group," excludes species (2), which appellants state is "analogous" or "equivalent" to species (1). [FN12]

FN12. The provisos actually exclude more than species (1) and (2). For example, polymers similar to species (1) and (2) but having substituted ring structures are also excluded.

Claims 64 and 71 are illustrative of the group of claims (claims 64 and 68-72) rejected under 35 U.S.C. s 112, first and second paragraphs:

64. A substantially linear thermoplastic polyarylene polyether composed of recurring units having the general formula:

-(O-E-O-E')-

where E is the residuum of a dihydric phenol and E' is the residuum of a benzenoid compound having one or more inert electron withdrawing groups in at least one of the position (sic, positions) ortho and para to the valence bonds having a sigma * value sufficient to activate a halogen atom and where both of said residuum (sic, residua) are valently bonded to the ether oxygens through aromatic carbon atoms with the provisos that E and E' may not both include a divalent carbonyl group linking two aromatic nuclei. (Emphasis added.)

71. The process for preparing substantially linear polyarylene polyethers which comprises reacting substantially equimolar amounts of an alkali metal double salt of a dihydric phenol with a dihalobenzenoid compound having halogen atoms activated by an inert electron withdrawing group in at least one of the positions ortho and para to the halogen atom, under substantially anhydrous conditions and in the liquid phase of an organic solvent having the formula:

Image 14 (0.75 X 1) Available for Offline Print

in which R represents a member of the group consisting of monovalent lower hydrocarbon groups free of aliphatic unsaturation on the alpha carbon atom and, when connected together represents a divalent alkylene group, and Z is an integer from 1 to 2 inclusive. (Emphasis added.)

The Rejections

The sole reference relied upon by the examiner and the board is:

***1014** Claims 1-9, 64, and 68-70 were rejected under 35 U.S.C. ss 102 or 103 as unpatentable in view of the Netherlands patent, which is a foreign-filed counterpart of appellants' 1963 application.

Before the PTO, appellants conceded that the invention was fully disclosed in the Netherlands patent. However, appellants contended that the claims are entitled to the benefit of the 1963 filing date under 35 U.S.C. s 120, [FN13] and therefore the Netherlands patent is not available as a prior art reference.

FN13. s 120. Benefit of earlier filing date in the United States.

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States by the same inventor shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application. (Emphasis added.)

The examiner and the board were of the view that the claims are not entitled to the 1963 filing date because the presently claimed subject matter is not "described" in the 1963 application as required by the first paragraph of 35 U.S.C. s 112. [FN14] As explained by the board:

FN14. s 112. Specification. The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention. (Emphasis added.)

The question determinative of the issue at hand is thus whether or not appellants are entitled to the filing date of their parent application Serial No. 295,519, i. e., July 16, 1963. An answer to this question quite obviously depends on what is the invention defined by the instant claims. It is the same as the one disclosed in (the) parent case or does it differ therefrom in a manner which

precludes the instant claims from being afforded the filing date of the parent case?

Under the rationale of the CCPA as set forth in In re Welstead, 463 F.2d 1110, 59 CCPA 1105, 174 USPQ 449 (compare also In re Lukach et al., 442 F.2d 967, 58 CCPA 1233, 169 USPQ 795, and In re Smith ((I)), 458 F.2d 1389, 59 CCPA 1025, 173 USPQ 679), which we deem controlling, we are constrained to conclude that the present claims are not entitled to the filing date of appellants' parent case Serial No. 295,519. The claims at issue contain provisos that E and E' may not both include a divalent sulfone group and may not both include a divalent carbonyl group linking two aromatic nuclei. The artificial subgenus thus created in the claims is not described in the parent case and would be new matter if introduced into the parent case. It is thus equally "new matter," i. e., matter new to the present application for which no antecedent basis exists in the parent case. Consequently, appellants are not entitled to rely on the filing date of their parent case to support a new subgenus for which no basis exists in the parent case. The reason why appellants now limit their claims to exclude those species eliminated by the provisos, i. e., loss in an interference, is manifestly immaterial.

Having reached the conclusion that appellants are not entitled to the filing date of their parent case for the subject matter defined by the present claims which delineate a new subgenus not described in the parent case, it follows that the Netherlands patent is a valid reference which, by appellants' own admission, fully meets the claims. The indicated rejection of claims 1-9, 64 and 68-70 under 35 U.S.C. 102 as unpatentable over the Netherlands patent is thus affirmed. The alternative reliance by the Examiner on Section 103 is inconsequential, Section 102 of the statute being the epitome of Section 103. In ***1015** re Pearson, (Cust. & Pat.App.), 494 F.2d 1399, 181 USPQ 641.

Claims 64 and 68-72 were rejected under 35 U.S.C. s 112, first and second paragraphs. In his Answer, the examiner stated that the claims were rejected under s 112, first paragraph, for "being broader than the enabling disclosure" and under s 112, second paragraph, [FN15] for being "broader than the express limitations disclosed as defining the invention." The examiner said the "specific deficiencies of the claims and disclosure" are that the expression "to activate a halogen" (claim 64) is "indefinite" because "it does not specify toward what the activation is" and that "(t)he express disclosure is clearly limited to the sigma * value recited in claim 1, for example: see ((A) and (B))."

> FN15. s 112. Specification.
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

In affirming the examiner on these rejections, the board stated:

> Further, claims 64 and 68-72 stand finally rejected under 35 U.S.C. 112 as being broader than the enabling disclosure (first paragraph) and broader than the express limitations disclosed as defining the invention (paragraph two).
>
> It is the Examiner's position that "to activate a halogen atom" (claim 64) is indefinite and that the disclosure also is limited to dihalobenzenoid compounds not broadly merely "activated by an inert electron withdrawing group" (claims 68-72) but the activation must have a sigma * value above about k0.7.
>
> We agree with this rejection. The specification makes it quite clear that a minimum sigma * activation value of the halogen atoms is required (note especially ((A))) and an undefined sigma * value thus lacks the requisite preciseness commensurate with the enablement of the disclosure.

OPINION

I. The Rejections of Claims 64 and 68-72 under s 112

Claims 64 and 68-72 were rejected under both the first and second paragraphs of 35 U.S.C. s 112.

[1] We begin with the rejections under the second paragraph of s 112. As stated in In re Moore, 439 F.2d 1232, 1235, 58 CCPA 1042, 1046-1047, 169 USPQ 236, 238 (1971):

> Any analysis in this regard should begin with the determination of whether the claims satisfy the requirements of the second paragraph. * * *
>
> This first inquiry therefore is merely to determine whether the claims do, in fact, set out and circumscribe a particular area with a reasonable degree of precision and particularity. It is here where the definiteness of the language employed must be analyzed not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be

interpreted by one possessing the ordinary level of skill in the pertinent art. (Footnote omitted.)

The examiner's s 112, second paragraph, rejection was premised on the general ground that the claims are "broader than the express limitations disclosed as defining the invention" and on two specific grounds: (a) that the expression "to activate a halogen atom" is "indefinite" because "it does not specify toward what the activation is;" and (b) that "(t)he express disclosure is clearly limited to the sigma * value recited in claim 1, for example: see ((A) and (B))." The board affirmed and stated: "an undefined sigma * value thus lacks the requisite preciseness * * *." (Emphasis added.)

Ground (a) focuses on the specific phrase "to activate a halogen atom." But the language is found only in claim 64, not in claims 68-72. Claim 68 recites "a dihalobenzenoid compound having halogen atoms activated by an inert electron withdrawing group," and claims 71 and 72 have a similar recitation. (Claims 69 and 70 depend from ***1016** claim 68.) Those recitations clearly specify "toward what the activation is," as the examiner would require. Ground (a), therefore, lacks merit with respect to claims 68-72.

[2] Product claim 64 [FN16] defines the complete polymer structure by describing the constituents partially in terms of their functions in the reaction and by their linkage into the end-product polymer. The specification provides further guidance on the meaning of the E' term:

> FN16. Claims 68-70 are product-by-process claims.

> It is seen also that as used herein, the E' term defined as being the "residuum of the benzenoid compound" refers to the aromatic or benzenoid residue of the compound after the removal of the halogen atoms on the benzenoid nucleus. (Emphasis added.)

It is also clear from the specification as a whole, that two keys to the polymerization reaction are inert electron withdrawing groups particularly positioned on the benzenoid nucleus and a cumulative sigma * value attributable to those withdrawing groups which is sufficient to activate a halogen atom on that nucleus. If the sigma * value is not sufficient to activate a halogen atom on the benzenoid nucleus, the reaction will not take place and the polymer will not be made. See In re Angstadt, 537 F.2d 498, 190 USPQ 214 (Cust. & Pat.App.1976). The specification adequately details which sigma * values are sufficient to carry out the reaction, and any person skilled in the art would immediately recognize from the above-quoted portion of the disclosure or the specification as a whole that the halogen atom mentioned in claim 64 was on the benzenoid nucleus prior to the reaction. It is clear that those skilled in the art would have no trouble ascertaining whether any particular polymer falls within the scope of claim 64. See In re Goffe, 526 F.2d 1393, 188 USPQ 131 (Cust. & Pat.App.1975). The questioned limitation is merely surplusage, since the claim would be definite with or without it. [FN17]

> FN17. We do not speculate on whether or not the claim would be unduly broad if the questioned limitation were removed. But undue breadth is not indefiniteness. In re Borkowski, 422 F.2d 904, 57 CCPA 946, 164 USPQ 642 (1970). This claim is definite either with or without the phrase "to activate a halogen atom."

[3][4] The point made by the board, that "an undefined sigma * value" lacks "preciseness," is also unsound. [FN18] Claim language must be read in light of the specification as it would be interpreted by one of ordinary skill in the art. In re Moore, supra. As pointed out above, those skilled in the art will be able to determine immediately from appellants' detailed specification what level of activation (i. e., sigma * value) is necessary to practice the invention. Cf. In re Mattison, 509 F.2d 563, 184 USPQ 484 (Cust. & Pat.App.1975). We conclude that the subject matter embraced by claims 64 and 68-72 is definite and that the claims set out and circumscribe a particular area with a reasonable degree of precision and particularity. In re Angstadt, supra; In re Skoll, 523 F.2d 1392, 187 USPQ 481 (Cust. & Pat.App.1975); In re Watson, 517 F.2d 465, 186 USPQ 11 (Cust. & Pat.App.1975); In re Moore, supra. Therefore, the rejection of claims 64 and 68-72 under the second paragraph of 35 U.S.C. s 112 is reversed.

> FN18. In re Merat, 519 F.2d 1390, 186 USPQ 471 (Cust. & Pat.App.1975), cited be the Solicitor, affirmed a s 112, second paragraph, rejection because the same word ("normal") was used in the claims in one sense and in the specification in a different

sense, thus rendering the claims indefinite. There is nothing akin to the Merat situation here.

The examiner's general ground and his ground (b) raise a lack of enablement issue properly arising under the first, not the second, paragraph of s 112. Ground (b) simply supplies the examiner's reasoning in support of the rejection of the claims under s 112, first paragraph, as "broader than the enabling disclosure."

As appellants state, the crux of this lack of enablement rejection is that although the specification describes how the halogen atoms bonded to the diahalobenzenoid compound (the E' precursor compound) must be activated in order for polymerization to occur, ***1017** the claims at issue do not recite a numerical definition of the degree of activation (a minimum sigma * value) required from the electron withdrawing group. The PTO position is that the claims must recite a minimum sigma * value in order to conform the scope of the claims to the scope of enablement provided by the specification. The PTO relies on statements (A) and (B) to prove that the scope of enablement provided by the specification is not commensurate with the scope of the claims.

[5] First, we note that it is the function of the specification, not the claims, to set forth the "practical limits of operation" of an invention. In re Rainer, 305 F.2d 505, 509, 49 CCPA 1243, 1248, 134 USPQ 343, 346 (1962). One does not look to claims to find out how to practice the invention they define, but to the specification. In re Roberts, 470 F.2d 1399, 1403, 176 USPQ 313, 315 (Cust. & Pat.App.1973); In re Fuetterer, 319 F.2d 259, 50 CCPA 1453, 138 USPQ 217 (1963).

[6] Second, we note that the specification as a whole must be considered in determining whether the scope of enablement provided by the specification is commensurate with the scope of the claims. In re Moore, supra, 439 F.2d at 1235, 58 CCPA at 1047, 169 USPQ at 238-39.

The present specification includes broad statements such as: "Any electron withdrawing group can be employed as the activator group in these compounds." The specification also discusses preferred embodiments, alternative embodiments, and the practical limits of operation.

Statement (A) describes preferred embodiments and practical limits of operation. It says that electron withdrawing groups having a high sigma * value ("preferably above 1.0") are preferred and that the practical limit of operation of the polymerization reaction is reached when the electron withdrawing group has a sigma * value of 0.7 (at that value the reaction rate "may be somewhat low").

Statement (B) describes an alternative embodiment ("a plurality of electron withdrawing groups") and the practical limit of operation for this embodiment. It states that the cumulative sigma * influence should be "at least about k 0.7."

[7][8] The PTO would limit appellants to claims reciting a sigma * value of at least 0.7. This view is improper because it requires the claims to set forth the practical limits of operation for the invention and it effectively ignores the scope of enablement provided by the specification as a whole. As we said in In re Goffe, 542 F.2d 564, 567, 191 USPQ 429, 431 (Cust. & Pat.App.1976):

> (T)o provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts. See In re Fuetterer, 319 F.2d 259, 265, 50 CCPA 1453, 1462, 138 USPQ 217, 223 (1963). (Footnote omitted.)

The rejection of claims 64 and 68-72 under the first paragraph of 35 U.S.C. s

112 is reversed. II. The Rejection of Claims 1-9, 64, and 68-70 Under s 102 or s 103, Raising Issues Under s 112 and s 120

[9] We are convinced that the invention recited in claim 1 is "disclosed in the manner provided by the first paragraph of section 112" in the 1963 application and that claim 1 is therefore entitled to the benefit of the 1963 filing date. [FN19] The only inquiry is whether, after exclusion from the original claims of two species specifically disclosed in the 1963 application, the 1963 disclosure ***1018** satisfies s 112, first paragraph, for the "limited genus" [FN20] now claimed.

FN19. Appellants have not argued the claims separately, thus, claims 2-9, 64, and

68-70 stand or fall with claim 1.

FN20. Appellants refer to the subject matter recited in claim 1 as a "limited genus." The board called it an "artificial subgenus." We use appellants' terminology. Whatever the label, the issue is the same.

While the board found that "no antecedent basis exists in the parent case" for the "limited genus" in claim 1, we see more than ample basis for claims of such scope. The 1963 disclosure is clearly directed to polymers of the type claimed. Fifty specific choices are mentioned for the E precursor compound, a broad class is identified as embracing suitable choices for the E' precursor compound, and twenty-six "examples" are disclosed which detail fifteen species of polyarylene polyethers. Only fourteen of those species and twenty-three of the "examples" are within the scope of the claims now on appeal. Two of the many choices for E and E' precursor compounds are deleted from the protection sought, because appellant is claiming less than the full scope of his disclosure. But, as we said in In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (Cust. & Pat.App.1976):

> Inventions are constantly made which turn out not to be patentable, and applicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable.

[10] It is for the inventor to decide what bounds of protection he will seek. In re Saunders, 444 F.2d 599, 607, 58 CCPA 1316, 1327, 170 USPQ 213, 220 (1971). To deny appellants the benefit of their grandparent application in this case would, as this court said in Saunders :

> * * * let form triumph over substance, substantially eliminating the right of an applicant to retreat to an otherwise patentable species merely because he erroneously thought he was first with the genus when he filed.

The board cited as "controlling" the decisions of this court in In re Welstead, 463 F.2d 1110, 59 CCPA 1105, 174 USPQ 449 (1972); In re Lukach, 442 F.2d 967, 58 CCPA 1233, 169 USPQ 795 (1971); and In re Smith, 458 F.2d 1389, 59 CCPA 1025, 173 USPQ 679 (1972). Those decisions, because of important factual distinctions, are not controlling.

In Welstead the applicant was attempting to introduce into his claims a new subgenus where " * * * the specification * * * contained neither a description * * * of the (subgenus) * * * nor descriptions of the species thereof amounting in the aggregate to the same thing * * *." Welstead conceded the absence from his disclosure of compounds of the "second type" within the new subgenus. Welstead is thus clearly distinguishable from the present case, in which appellants' grandparent application contains a broad and complete generic disclosure, coupled with extensive examples fully supportive of the limited genus now claimed. Indeed, Welstead might have well been cited by the board in support of a decision contrary to that reached, in view of what this court there implied concerning the possibility that "descriptions of species amounting in the aggregate to the same thing" may satisfy the description requirements of 35 U.S.C. s 112, paragraph one.

Similarly, in Lukach we noted that " * * * the grandparent application here does not disclose any defined genus of which the presently claimed copolymers are a subgenus." That is not the fact here. Appellants' grandparent application clearly describes the genus and the two special classes of polymer materials excluded therefrom.

In Smith the applicant sought the benefit of his prior application for a broadened generic claim, replacing the claim limitation "at least 12 carbon atoms * * * " with a new limitation calling specifically for 8 to 36 carbon atoms, where there was no disclosure of either the range itself or of a sufficient number of species to establish entitlement to the claimed range. Appellants, in contrast to the applicant in Smith, are narrowing their claims, and the full scope of the limited genus now claimed is supported in appellants' earlier application, generically and by specific examples.

***1019** The notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species therewithin, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirements of s 112, first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of the statute. All that happened here is that appellants narrowed their claims to avoid having them read on a lost interference count.

The board indicated that "it is manifestly immaterial" why appellants limited their claims. Though it is true that insufficiency under s 112 could not be cured by citing the causes for such insufficiency, it is not true that the factual context out of which the question under s 112 arises is immaterial. Quite the contrary. Here, as we hold on the facts of this case, the "written description" in the 1963 specification supported the claims in the absence of the limitation, and that specification, having described the whole, necessarily described the part remaining. The facts of the prosecution are properly presented and relied on, under these circumstances, to indicate that appellants are merely excising the invention of another, to which they are not entitled, and are not creating an "artificial subgenus" or claiming "new matter."

In summary, and for the reasons discussed, the rejections of claims 64 and 68- 72 under s 112, first and second paragraphs, are reversed ; appellants' 1963 disclosure satisfied s 112, first paragraph, with respect to claims 1-9, 64, and 68-70 and appellants are, therefore, entitled to the benefit of their 1963 filing date under 35 U.S.C. s 120. The Netherlands patent is thus rendered unavailable as a prior art reference, and the rejection of the claims under 35 U.S.C. ss 102 or 103 is reversed.

REVERSED

LANE, Judge, dissenting in part.

I would affirm the rejection of claims 64 and 68-72 under s 112, paragraphs 1 and 2, because the specification indicates that a minimum sigma value of k 0.7 is an essential requisite. These claims fail to recite this requisite, thus fail to define appellants' invention and are broader than the disclosure. I concur in reversing the rejection of claims 1-9.

END OF DOCUMENT